

How to select of a Topic and design study for Ayurveda Thesis?

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Scientific inquiry is seeing what everyone else is seeing, but thinking of what no one else has thought.

A. Szentgyorgyi, 1873 (he won the Nobel Prize for isolating Vitamin C)



Topics covered

- Introduction
- Need for Study / Research & Selection of problem
- Writing hypothesis / research Objective
- Review of Literature including literature search
- Points to be considered about Research Design
- Considerations about Interventions

Introduction

- The growing popularity of Ayurveda around the globe created new challenges to the Ayurvedic fraternity.
- Although Ayurveda is Practical and Clinical oriented, there is need of systematized scientific research, for this both philosophy and science are equally important as quoted by **Einstein “philosophy without science is blind and science without philosophy is lame”**.
- With sound scientific evidence, modern world will accept the Ayurveda.

- A **thesis** (Often Bachelors/Masters) or **dissertation** (often Doctoral) is a document submitted in support of candidature for an professional qualification (MD / MS (Ayurveda) presenting the author's research and findings.

(International Standard ISO 7144: Documentation—Presentation of theses and similar documents, International Organization for Standardization, Geneva, 1986.)

Research during postgraduation is as Partial-Fulfillment of PG Curriculum

- ***Synopsis or Protocol***
- A document that states the background, objectives, rationale, design, methodology (including the methods for dealing with *AEs, withdrawals etc.*) and *statistical considerations of the study.*

Why Research needed in Ayurveda?

- To validate the principles & practices told in the classics in specific disease or condition/stage of disease
- To develop safe, effective & economical new drug or formulation
- To find the new actions of the drug or formulation
- To find out new nidana & their role in samprapti
- To develop new analytical tools for QC
- To study the actions of currently used dietetics

General Considerations

- Evaluate Ayurveda in its own theoretical framework
- Evaluate Ayurveda in the theoretical framework of Conventional Medicine
- Compare the efficacy of Ayurveda Medicine and/or Conventional Medicine;
- Compare the efficacy of different traditional medicinal systems

Methods of Research in Ayurveda

Chaturvidha Pareeksha

- Literary review – Aptopadesha
- Hypothesis- Anumana
- Selection of patients – Aptopadesha, Pratyaksha
- Interventions- Yukti
- Assessment- Aptopadesha, Pratyaksha,
Anumana

Methods of Research in Ayurveda

Pancha Avayava

- Pratijna- Defining Problem/Hypothesis / Objective
 - Sthapana- +ve hypothesis
 - Pratishtapana- null hypothesis
- Hetu – Reasoning (Need for the study) - Pratijna should be Sahetuka (why you have taken research?)
- Udaharana- (experimental) - Observations & results
- Upanayana- Uhapoha- (Discussion & interpretation)
- Nigamana- Conclusion (recalling the Pratijna, whether the Pratijna proved or disapproved)

Steps involved in Ayurveda Research

- Selection of Areas of Research /defining problem / formulating researchable question / formulation of hypothesis
- Review of Literature
- Formulating Hypothesis and Research Objective
- Planning of Research (Research Design)
- Submitting it as a research proposal for Ethics Committee & University / Funding agency approval
- Implementation of the research project
- Data Collection, Data Analysis & Interpretation
- Publishing the research findings

Good Research Problem

Criteria – Good Research Problem

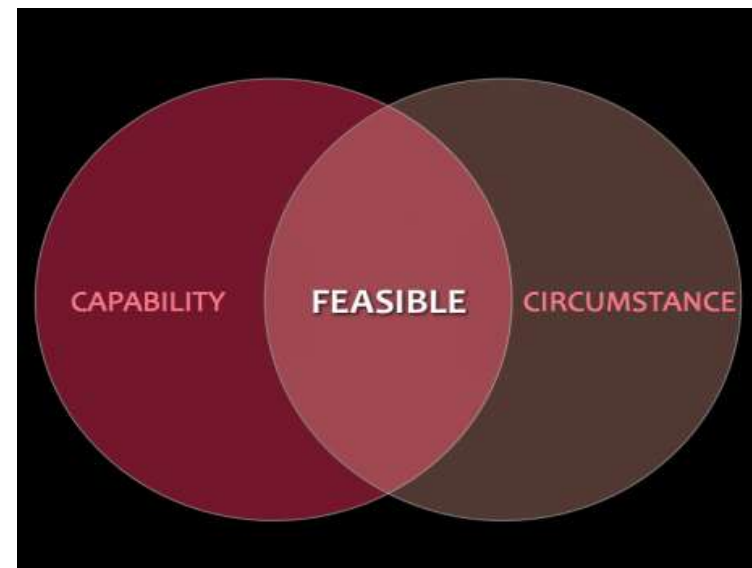
“FINER “

While considering

- **F= Feasible**
- **I= Interesting**
- **N= Novel**
- **E= Ethical**
- **R= Relevant**
- **P=Population**
- **I=Intervention**
- **C=Control**
- **O=Outcome**

Feasible

- Sufficient resources in terms of time, staff, and
- funding
- Use of appropriate study design
- Manageable in scope
- Adequate sample size
- Trained research staff



Interesting

- Interesting as a researcher or guide
- Investigator's motivation to make it Interesting

Novel

- Confirms, refutes or extends previous findings
- Provides new findings
- Thorough literature search New findings or
- extension of previous findings
- Guidance from mentors and experts

Ethical

- Following ethical-guidelines
- Regulatory approval from IEC/
Institutional Review Board



Relevant

- To scientific knowledge
- To clinical and health policy
- To future research
- Influence on clinical practice / Ayurveda
- Furthering research and health policy



Selection of Research problem (Areas of Research)

Steps in identifying a research problem in Ayurveda

- **Step 1** : Determining the field of research in which a researcher is keen to do the research work.
- **Step 2** : The researcher should develop the mastery on the area or it should be the field of his specialization.
- **Step 3** : He should review the researches conducted in area to know the recent trend and studies in the area.

Steps in identifying a research problem

- **Step 4:** On the basis of review, researcher should consider the priority field of the study.
- **Step 5:** Researcher should draw an analogy and insight in identifying a problem or employ personal experience of the field in locating the problem / gap in the current knowledge. may take help of guide or expert of the field.
- **Step 6 :** Researcher should pin-point specific aspect of the problem which is to be investigated.

Ayurveda Postgraduation...

MD (Ayurveda)

- Ayurveda Samhita and Siddhanta
- Rachana Sharira
- Dravyaguna Vigyana
- Rasashastra & Bhaishajya kalpana
- Kaumarabhritya
- Swasthavritta & Yoga
- Kayachikitsa
- Mano Vigyan Avum Manasa Roga
- Roganidan Avum Vikriti Vigyan
- Panchakarma
- Agada Tantra Avum Vidhi Vigyan

MS (Ayurveda)

- Shalya Tantra
- Prasuti tantra & Striroga

Practical Steps

In Clinical specialties / Applied Study

- Choose one / two Srotas which really evokes interest in you and guide also has agreement and expertise on that.
- Survey the OPD / IPD register and about availability of Patients / subjects
- Brainstorm among your classmates about their choice of thesis topic / disease.
- Discuss with your guide about your choice of area and come to a common point

Practical Steps

In Clinical specialties / Applied Study

- You have to answer certain questions?
 - Why you have chosen particular disease? Specific disease condition / Roga / Doshavastha?
 - Why you have chosen specific treatment / procedure / regimen? (Justification with relevant scientific background is very important)
 - If you are comparing, you have to give reason. advantage of new treatment / procedure / over oral / other treatment needs to be clearly mentioned?
 - Source or reference about specific action or use / indication is very essential

Practical Steps

In Clinical specialties / Applied Study

- Most important point about selection of problem
 - Problem should be relevant to your speciality
 - You need to “just” specifically state the problem rather than explaining problem
 - If you can define the Problem properly, your research has real meaning

Areas of Research

MD (Ayurveda) - Kaumarabhritya

- Pranavaha – Kasa, Pratishyaya (Recurrent URTI), Tamaka Shwasa (childhood asthma), Tundikeri (tonsillitis)
- Annavaha – Grahani Dosha, Krimi (Kosthagata)
- Raktavaha – Pandu (IDA) Thalassemia (Beejadushtijanya Pandu),
- Mootravaha – Shyyamutra
- Sarvadhātu – Karshya in children
- Mamsa, Majjavaha - Vataavaha – cerebral palsy
- Manovaha – ADHD, on IQ of school going children mental retardation

Areas of Research

MS (Ayurveda) – Shalya Tantra

- Surgically managed condition : ??
- Conditions Managed with parasurgical measures (Kshara/Kshara Sutra): Arsha / Arsha (with Kasisadi Taila)/ Bhagandara (Fistula-in-ano) / Parikartika (chronic fissure-in-ano) (with Kshara Sutra)
- Conditions Managed with parasurgical measures (Agni): Gridharsi / Katishoola / Sandhigata Vata (Cervical spondylosis/OA of Knee joint)
- Conditions Managed with parasurgical measures (Jalaukavacharana): thrombosed piles

Areas of Research

MS (Ayurveda) – Shalya Tantra

- Conditions Managed with local measures :
Dushta Vrana (Diabetic ulcer)
- Conditions Managed with oral medications:
Arbuda Gala Laryngopharyngeal Carcinoma,
Asthi-bhagna / Closed Upper Limb Fractures /
Mootraashmari (Paniya Kshara) / Mootraghata
(BPH) / Simple fracture
- Pre-Anaesthetic Effect of certain drugs:

Areas of Research

MS (Ayurveda) – Prasuti Tantra & Stree Roga

- Prasuti Tantra
- Pregnancy –
 - 1st trimester – Garbhini Cchardi
 - 2nd trimester – Kikkisa
 - 3rd trimester – Kikkisa
 - On Prasava – Basti Karma, oral medicines
- Garbhini related complications - Garbhini Mutrakricchra, Putraghni Yoni Vyapad (habitual abortion), Garbhini Pandu, gestational hypertension

Areas of Research

MS (Ayurveda) – Prasuti Tantra & Stree Roga

- Stree Roga
 - Infertility (Vandhyattva) : ovarian factor (anovulation) / tubal factor (tubal blockage) / cervical factor / endometrial factor
 - Menstrual diseases: Kasthartava (Dysmenorrhoea) / Artava-Kshaya / Asrigdara / Alpartava / Shwetapradara
 - Menopausal syndrome / Postmenopausal Osteoporosis
 - Diseases : Arbuda (uterine fibroid), Garbhashaya Greevamukhagata Vrana (cervical erosion)

Approach towards preparing synopsis in Basic Principles

- Can be Literary or Applied research
- Choose Basic Principle / Nyaya / Vada
- Choose Basic Principle and do applied study (may in human / animal / in vitro model)
- Choose a chapter and study in depth
- Choose Manuscript and editing
- Vast opportunity to standardize basic concepts of Ayurveda
- Requires lot of involvement

Approach towards preparing synopsis in Rachana Sharir

- Choose a basic Rachana Sharir concept – do cadaveric study
- Pramana Sharir -
- Marma Sharir

Areas of Research

MD (Ayurveda) - Dravyaguna

- Rasa – Effect of Rasa Atiyoga on various systems - pharmacological (animal) studies
- Activity- Anti-Hyperlipidemic (ex. Vacha), Antipyretic and Analgesic Activities (ex. Chirabilva), Antispasmodic and Muscle Relaxation Activity (ex. Patha) hepatoprotective (Ex. Dronapushpi) –pharmacological (animal) studies
- Karma – Deepana (Vidanga), Kasahara (Kanthakari), Mootrala (Kusha), Shvasahara (Tamraparna), Vishaghna, Vrishya (Putranjeevaka) - pharmacological (animal) studies with applied clinical studies

Areas of Research

MD (Ayurveda) - Dravyaguna

- Disease specific indication (Ex. : Amavata, Amlapitta, EHT, Grahani, Kushtha, Vicharchika, Khalitya, Madhumeha, Sthaulya, Tamaka Shwasa) - pharmacological (animal) studies with applied clinical studies
- Identification of various sources of plants including adulterant – pharmacognostico-phytochemical studies
- Study on Paryaya drugs - pharmacognostico-phytochemical studies
- Compare the parts of various species of plant about claimed effect (Ex. Bala moola, seeds of Dadima) - pharmacognostico-phytochemical studies

Approach towards preparing synopsis in RSBK

- All basic Bhaishajya Kalpana - variations
- Standardization of thousands of formulations
- Variation in preparation methods and their effect on clinical outcome
- Shelf life study
-
-

Approach towards preparing synopsis in Roga Nidana

- Diagnostic standards of all the Ayurvedic diseases
- Pariksha....
- Upashayatmaka study
- Mostly requires survey study with larger sample size
- Ample scope for development of scales for assessment

Approach towards preparing synopsis in Agada Tantra

- Role agada in diseases – Vicharchika (Agada Prayoga)
- May be in human or animal model
- Vishavaidya Practices – Field survey

Review of Literature

Review of Literature

- You have to review the relevant literature / concepts from classics, previous thesis, Ayurveda journals and latest research updates from databases.
- First of all, define the basics i.e. disease/ conditions/concept clearly “**with relevant references**”.

In Review of Literature you should...

- Collect all the relevant materials (with reference)
- Compile the literature keeping in mind about the research problem and hypothesis in mind
- Synthesis the concept so as to reflect as all aspect / facets of research problem and topic

Offline & Online Resources

Samhita, E-Samhita, e-resources

Old Thesis

Medical Search Engines: Pubmed, Google scholar, RGUHS-Helinet, Medknow Journals, MedInd

Journal Websites – Ayurveda and Biomedicine

General Websites about Medicine

General Websites related to Ayurveda

Searching E-Samhitas for Words

Charaka Samhita

Sushruta Samhita

Astanga Hridaya & Sangraha

>20 Nighantu

Madhava Nidana

You can copy & paste also to MS Word & PPT too..

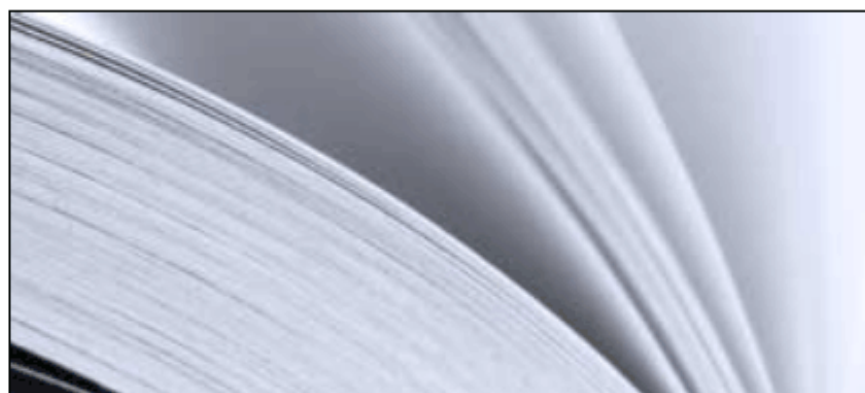
First line of search should be

SEARCH

www.scholar.google.com

Always login with your gmail id

Search Pubmed for
Research Articles



PubMed

PubMed comprises more than 21 million citations for science journals, and online books. Citations may include Central and publisher web sites.

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- Most Important is

—DECIDE OR PIN
POINT THE TOPIC/S
YOU WANT TO
SEARCH

Formulating Hypothesis / Research Objectives

Formulating Hypothesis / Research Objectives

- It is the presumptive statement of a proposition, which the investigation seeks to prove. / simply it is the tentative, concept / experience based answer for the research problem
- Statement about the relationship between two or more variables (independent with dependent variable). So you have to identify the dependent / independent / extraneous variable)
- It is a verbal statement in a declarative form
- **It is pivotal in research**
- **State Alternate (H_1) and null hypothesis (H_0)**

Objectives – Primary / Secondary

- Should be

–S

–M

–A

–R

–T

Materials and Methods

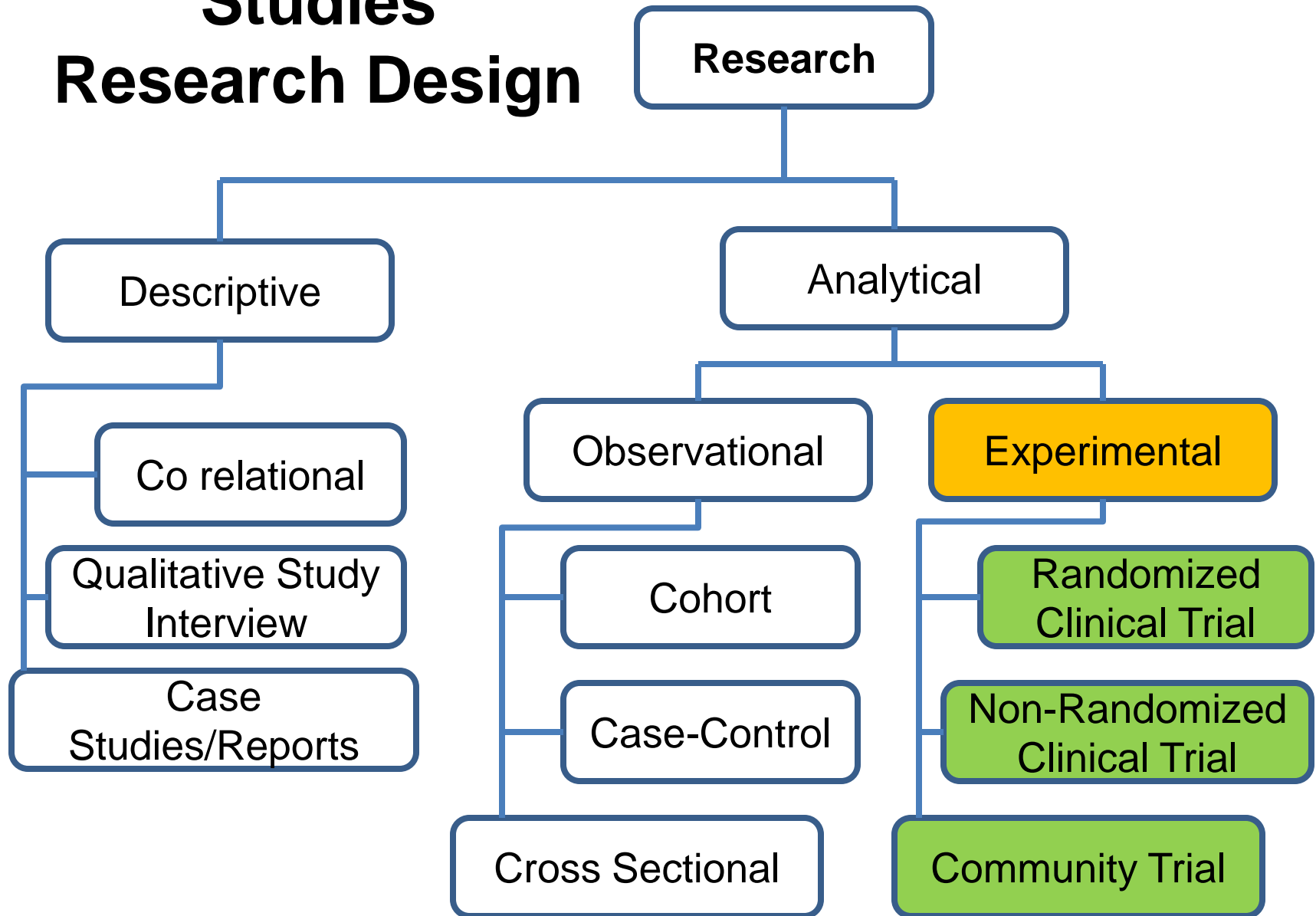
Research Design...

- Systematic step / approach towards solving the research problem
- is a choice of an investigator about the components of his project and development of certain components of the design.
- A design of research does not consists of an ordered sequential step by-step procedure.

Research Design

- It is a planning stage of research which is usually made logically visualizing its practicability.
- The selection of research components is done keeping in view of the objectives of the research.
- Research hypotheses also provide the basis for designing a research work.

Studies Research Design



While designing the clinical study you are supposed to consider



Good Clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine (GCP - ASU)

ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN PARTICIPANTS

Annex 08 - Good Manufacturing Practices: Supplementary Guidelines for the Manufacture of Herbal Medicinal Products

© World Health Organization
WHO Technical Report Series, No. 863, 1996

or Schedule Y, the following Schedule shall be substituted, namely :-

“SCHEDULE Y

s[See rules 122A, 122B, 122D, 122DA, 122E

GUIDELINES FOR PERMISSION TO IMPORT AND / OR
SALE OR TO UNDERTAKE CLINICAL TRIALS

**WHO guidelines on
good agricultural and collection practices
(GACP)
for medicinal plants**

Considerations: Research Design

- The Ayurvedic design of clinical trials conforms to one of the following: **(may be Open label / single blinded / double blinded)**
- **Single arm clinical study**
- **Two / more than groups**
- Non-randomized, placebo controlled clinical study
- Non-randomized, active controlled clinical study
- Non-randomized, multiple arm clinical study
- **Randomized parallel group** clinical study
- Randomized, parallel group, placebo controlled
- Randomized, parallel group, active controlled
- **Randomized, parallel group, multiple arm** clinical study
- Randomized, crossover clinical study

- Double blind, randomized, placebo controlled, multicentred clinical study is not the always acceptable design for Ayurveda Clinical Trials.
- In trials of Ayurvedic medicines other designs needs to be also be used.

In clinical study involving human participants...

- Study may be conducted to
 - Diagnose
 - Prognosticate
 - Treat / manage
 - Prevent a disease / condition
- With help of Pariksha (lab test / investigations), medicines / procedures / Ahara / Vihara

Interventional Trial

- An interventional trial is one that prospectively assigns human participants or groups of humans to one or more health-related intervention to evaluate the effect on outcomes.

- The level of evidence on efficacy of Ayurvedic medicines can be significantly increased by well designed
- **management trial design/**
- **blackbox design**

Management / Pragmatic trial design

- can also be included to see the combined effect of Panchakarma / procedures, palliative therapy & Pathyapathya to prove the safety & efficacy of Ayurveda.
- In case of Panchakarma comparing the procedures is best way and if not possible then compare with palliative medicine.

Black-box design

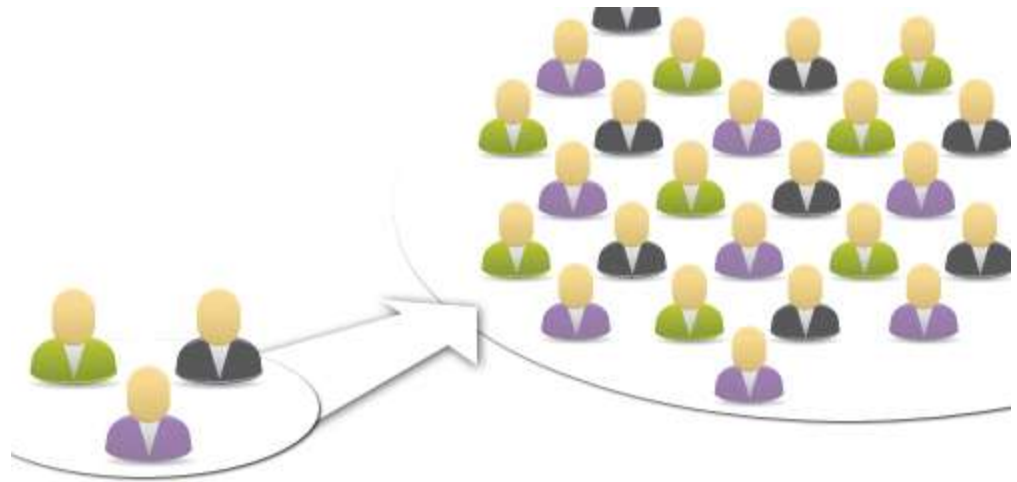
- The study of Ayurvedic medicine can also be undertaken in a “black-box” manner.
- This means that the treatment and all of its components are delivered as they would be in the usual clinical situation.
- In this type of study, no component of the treatment “package” is isolated and studied independently.

Source of Data / Selection of patients

- Patients should be selected irrespective of sex, religion, social status etc.
- Any potential bias in patient selection, recruitment and enrolment should be eliminated.
- **Most of PG Ayurveda research sampling is convenience sampling**

Sample size

- The number of patients in a study needs to be adequate, in order to determine any clinically important differences between the study groups.



Diagnostic criteria

- A clear practically possible diagnostic criteria should be defined based on the classical references for every disease with accepted modern diagnostic criteria if required modified.

Inclusion criteria

- Specifications of the subjects (patients / healthy volunteers) about
 - age,
 - gender,
 - ethnic groups,
 - ranges prognostic factors
- Chronicity consideration is very important
- **Important : Those patients who are ready to sign informed consent form will be included**
 - In Kaumarabhritya – Informed assent from parents/guardians

- While selecting the patient consideration of Prakruti, Dosha, Dooshya, Agni Bala, Koshtha, Shareera Bala, Agni Bala, Satva Bala, Sadhya-Asadhyata are essential.

Exclusion criteria

- **Exclude confounding disease conditions among the included patients**
- **Concurrent medicines**
- **Lab tests / examination to rule out diseases**
- Generally Ati-Teekshnagni, Ati-Mandagni, Ati-sthula, Ati-Krishna, Ati-Deergha, Ati-Hrisva should be excluded
- Ati-loma or Aloma patients should be excluded for Abhyanga, Lepa, Udvartana etc. therapies.
- **Pregnant or lactating females. Some mineral and Poisonous herbal drugs and abortifacient drugs.**

Exclusion criteria....

- Use of any Ayurvedic / conventional medicine within 15 days of study medication initiation
- Sadhya-Asadhyata Lakshana told in the classics should be considered
- Presence of upadrava and their severity, duration, frequency
- Discontinuation criteria for study subjects and instructions on terminating or suspending the whole study or a part of the study

Exclusion criteria....

- Active metabolic or gastrointestinal diseases that may interfere with nutrient absorption, metabolism, or excretion.
- Subject taking daily medications or dietary supplements at doses that would interfere with Agni / nutrient absorption, metabolism, excretion or gastric motility.

Grouping / Randomization

- Randomization of groups to eliminate bias has been a major advance in therapeutic evaluation of both synthetic and Ayurvedic medicines.
- **The main purpose is to eliminate selection bias and balance known or unknown confounding factors in order to create a control group that is as similar as possible to the treatment group.**
- **Random Allocation software / site** can be used effectively

<http://www.randomizer.org/>

Methods of Random Assignment

- Coin toss, lottery, toss of dice, shuffling cards etc
- Online tool
- Random number table
- Computer generated randomization
- Permuted block randomization, fixed
- Permuted block randomization, variable
- Stratified randomization
- Stratified block randomization
- Adaptive randomization, such as minimization
- Other, describe

Blinding/masking

- Blinding refers to methods used to prevent participants and investigators from knowing what interventions are being used to reduce bias.
- Masking refers to the methods used to camouflage interventions to achieve blinding.
- **Open label clinical study is the rule of Ayurveda study**
- **Virtually not possible to blind and mask**

Types of blinding

- **Open label**
- **Participant blinded**
- **Investigator blinded**
- **Outcome assessor blinded**
- Double blind double dummy
- Participant and Investigator blinded
- Participant and outcome assessor blinded
- Participant, investigator and outcome assessor blinded
- Participant, investigator, outcome assessor and data-entry operator/statistician blinded

Control groups

- A well-conducted and controlled clinical trial could provide sufficient evidence to establish a relationship between the use of a herbal medicine or Ayurvedic procedure-based therapy
- It is preferable to compare a herbal medicine / procedure with both a **well-established treatment / procedure** and another control group.
- Research on combinations of Ayurvedic and conventional medicine should always consider potential therapeutic interactions and side-effects.

Details of Ethics Clearance is Essential

- **Please mention**
 - **Name of Institutional Ethics Committee**
 - **IEC Number and date of approval for a specific period**

Considerations: Intervention

Intervention

- Drug – Classical reference, Source of raw drug, authentication, composition of formulation (Sanskrit name / English, part used / proportion), method preparation and packing details, analysis of prepared drug
- Dosage, Duration, Anupana (each of medicine used) / Standard operative procedure of Karma
- Follow up during study and after study
- Pathya Apathya

Considerations: Intervention

- The type of intervention must be clearly defined.
- In treatment using **herbal medicines**, this should also include, for example, information on the composition and manufacturing of finished herbal products. (GAP, GMP)
- In **Ayurvedic procedure based therapy**, this should include, for example, information on the tools and equipment used.

Considerations: Intervention

- In case of classical medicines reference, preparation method
- If the setting is an important component of a treatment, its essential features must be described.

Considerations: Intervention

- The dose, frequency and duration of a treatment must be described completely.
- “Dose” in Ayurvedic procedure-based therapies refers to a variety of attributes related to each course of the therapy.
- The “dose” used in any study should be based on the relevant literature and experience of Ayurvedic medical practitioners.
- The duration of follow-up should be clearly stated. Its length needs to be appropriate to the treatment carried out.

Shelf life or Stability of drug:

- Most of the medicines such as Choorna, Leha, Kashaya etc. are having shorter life span (compared to the trial period).
- So if the trial is for 2 years duration.
- There are two ways to solve this problem.
- **In such cases the trial drug should be prepared in 2 batches with strict batch-batch uniformity**
- Enhancing the shelf life of formulations

Dosage form

- Most acceptable
- Easy to administer
- Stable
- Having long shelf life
- Blinding (?)

Anupana

- Simple
- Easily available
- Uniform for all subjects
- Avoid using Specific Anupana in OPD cases.
- It should be used in admitted cases only.

Use of Placebo

- The use of an inert placebo is decreasing in comparative clinical trials because in most clinical conditions there already exists a treatment. The new herbal drug should therefore be compared against the standard /existing drug.
- **It would be unethical to withhold any treatment to a group of patients – if such treatment exists – for the sole purpose of investigating whether Ayurvedic medicine is effective.**

- In the case of herbal medicines with a strong flavour, placebo substances with the same flavour may have a similar function.
- In such cases, it may be advisable to use a low dosage of the same herbal medicine as a control. **(Ranjit Roy, WHO guidelines for Traditional Medicine)**
- Alternatively, a positive control, such as well-established treatment, can be used.

Contraindications for use of Placebo:

- Ca, AIDS, PT, CRF, complications of Diabetes (Nephropathy, retinopathy)
- But for prevention trials for the above said diseases can be undertaken after considering the ethical issues.

Follow-up

- The duration of follow-up should be clearly stated. (during treatment / after treatment)
- Procedures for monitoring subjects' **compliance (80%)**
- **Interval in which the patient / participants are to be followed up during and after study is important**
- **It determines statistical methods**

Subject withdrawal criteria & Concurrent / Rescue medicine

- (i.e. terminating investigational product treatment /
- study treatment) and procedures specifying – when and how to withdraw subjects
- from the treatment, type and timing of the data to be collected from withdrawn
- subjects, whether and how subjects are to be replaced and the follow-up on the
- withdrawn subjects.

Criteria for discontinuation and ADR recording

- Any ADE's
- Any ADR
 - Recording the side effect, adverse drug reaction, adverse drug event is essential part of clinical trial protocol

Number: Centre / Month / Year

**NATIONAL PHARMACOVIGILANCE PROGRAMME
FOR AYURVEDA, SIDDHA & UNANI (ASU) DRUGS**

Reporting Form for Suspected Adverse Reactions to ASU Drugs

- Please note :**
- (I) Information about the patients, prescribers and reporters will remain confidential.
 - (II) It is requested to report ALL suspected reactions as soon as possible, even if complete information is not available. Please note however that column numbers 1,2,3,4, 6 & 10 are compulsory.

1. Patient / consumer identification (please complete or tick boxes below as appropriate) :

Name /Identifier Initials

Patient's Record Number
(PRN):

Outcome Measures (Assessment Criteria)

- Outcome measures include the patient's perception of restoration of function, quality of life and functional status, as well as objective measures of mortality, morbidity and health status.
- Efficacy....
- Safety...



OUTCOME MEASURES (Assessment Criteria)

- appropriate to the research question.
- It may include quantitative and qualitative outcomes; primary and/or secondary outcomes; and generic and/or highly specific outcomes.
- Primary outcome measure should be specific to the disease (for eg. PASI scale in case of Psoriasis)
- secondary outcome measures if possible should be mentioned (for eg. DLQI for Skin Disease)

OUTCOME MEASURES

(Assessment Criteria)

- For all diseases assessment should be done on the basis of clinical symptoms, lab parameters, objective parameters
- For grading any symptoms consideration of severity, frequency and duration is essential.
- Parameters in numerical (BP, BMI etc.) should not be graded.
- The use of Charaka's assessment criteria should be clearly defined. It is most suitable in chronic generalized disorders.

Statistics of Synopsis...

Reference

- You have to master art of referencing
- Vancouver style of Referencing – RGUHS, Karnataka

Literary Study

BASIC PRINCIPLES SYNOPSIS

ASHWINI SAMHITA- CRITICAL EDITION OF MANUSCRIPT WITH ENGLISH TRANSLATION

BY

DR SHRIHARSHA

GUIDE

DR MALLIKA KJ

Objectives

- To explore, analyze and interpret the subject matter of Ashwini Samhite.
- To review the contributions of Ashwini Samhite.

**Literary research & doesn't
involve human
participants**

Basic Research / Applied Study

A STUDY ON DESHA SATMYA W.S.R. TO RAGI (ELEUSINE CORACANA) CONSUMING PEOPLE IN HASSAN

By
Dr. POONAM A PATEL

Guide :
Dr M G Yaligar

- **6.4 OBJECTIVES OF THE STUDY:**
- To study the concept of Desha Satmya by evaluating the health status of people consuming Ragi as a staple diet in Hassan.
- This is a survey study, using questionnaire

- **Plan of Study: CROSS SECTIONAL SURVEY**
- Urban and Rural areas of Hassan District will be selected on the basis of stratified random sampling method.
- Door to door survey will be carried out to select the volunteers as per convenience sampling.
- Minimum of 250 Volunteers above the age of 18 will be grouped based on consumption and non-consumption of Ragi as a staple diet.
- The health status of both groups will be assessed based on specially structured standard questionnaire.
- Health status, Nutritional status , Quality of life, Incidence of diseases, S/S related to aging

A STUDY ON ASSESSMENT OF LEKHANA KARMA OF LAUHA BHASMA IN STHAULYA

By

Dr. VIKAS BHARDWAJ

Guide

Dr Chethan

SHARIRA RACHANA SYNOPSIS

ANATOMICAL STUDY ON THE TYPES OF SNAYU BASED ON CADAVERIC DISSECTION

**By
Dr.AFIL M ALEX
Guide
Dr.UMA B GOPAL**

AIMS AND OBJECTIVES

- To reveal the structures of four types of Snayus on the basis of cadaveric dissection.

- **Cadaveric Study:**
- Dissection of the 2 cadavers will be carried out in the Dept. of Shareera Rachana, S.D.M. College of Ayurveda, Hassan.
- **METHOD OF COLLECTION OF THE DATA:**
- Dissection of cadaver will be performed and relevant data will be collected. Observations will be analyzed and co-related in the view of Ayurvedic description of four types of Snayu mentioned in different areas with special reference to contemporary science.
- **DESIGN OF STUDY**
- The preferable cadavers, minimum 2 in number will be selected for dissection. Observations on dissection will be compared and analysed on the basis of the conceptual data collected.

DRAVYAGUNA SYNOPSIS

A CLINICAL STUDY ON
NIDRAJANAK ACTION OF BIMBI OIL
[COCCINIA GRANDIS (L.)VOIGT]

BY

Dr. ABDURAHAMAN POILAN

GUIDE:

AIMS AND OBJECTIVES

- To evaluate the efficacy of Nidra janaka action of BIMBI taila on external application
- For physico- chemical evaluation of Bimbi Panchanga.

- **C: Inclusion criteria:**
- Patients of insomnia X 15 days to 4 years duration.
- Patients of either gender / age group 25- 50years.
- **D: Exclusion criteria:**
- Nidranasha due to Madatyaya, Abhighata and other systemic diseases, secondary insomnia. Pts on hypnotic rx or other drugs known to cause drowsiness.
- **E: Plan of study:** 60 Patients / 2 groups / each 30 patients.
- **Bimbi oil group:** Bimbi oil as Thala & Padabhyanga / evening time / for half an hour X 30 days.
- **Standard group:** Jatamansi kalka applied on the murdha bhaga & sole of the feet / evening time / for half an hour X 30 days.

Experimental / Analytical Study

AGADA TANTRA SYNOPSIS

A STUDY ON THE EFFICACY OF BILVADI YOGA IN PURIFYING THE POLLUTED WATER

**BY
DR. SANTHOSH H.S**

**GUIDE
Dr. Ashwinkumar S Bharati.
Reader and HOD
Department of PG Studies in Agada Tantra
SDM College of Ayurveda and Hospital, Hassan 573-201**

**CO-GUIDE
DR.JAYANTHA
Professor, Dept. of Civil Engineering,
MALANAD College of Engineering & Technology, HASSAN.**

6.4 OBJECTIVE OF THE STUDY:

- **1. To Evaluate the effect of Bilvadi Panchanga Yoga on different samples of polluted water**

Experimental Study with Animal Study

**AN EVALUATION OF
BHOOMYAMALAKI (*Phyllanthus
niruri* Sensus Hook.f.) SWARASA
FOR HEAMATINIC EFFECT IN
ALBINO RATS**

**By
Dr. ABDUL RAHMAN**

**Guide
Dr. Harini. A**

RSBK

SYNOPSIS

EXPERIMENTAL STUDY ON DYSLIPIDEMIC ACTIVITY OF RASONA KSHEERAPAKA PREPARED BY DIFFERENT METHODS

By

DR. JAYAPRAKASH.A.N.

Guide

DR. VINAY KUMAR .R. KADIBAGIL

EFFICACY OF DUSIVISHARI AGADA IN ACETAMINOPHEN (PARACETAMOL) INDUCED HEPATOTOXICITY IN WISTAR RATS

By

Dr.SREEJITH. G .S

Guide

Dr.ANITHA. M.G

CO-GUIDE

Dr.RAVISHANKAR.B

PHARMACEUTICO ANALYTICAL STUDY OF DURATION OF SNEHA PAKA W.S.R TO BRAHMI GHRITA AND ITS EFFECT ON MEMORY IN ALBINO RATS

By

DR.SARAN BABU

Guide

DR.VINAY. R. KADIBAGIL

C) ANALYTICAL STUDY INVOLVES

- The samples will be analyzed at SDM Research Center, Udupi; using following parameters as per the references available in protocol for testing published by CCRAS.
- 1. Organoleptic character: Colour, Odour, Appearance, Taste, Touch
- 2. Specific gravity
- 3. Refractive index at 25 °C
- 4. Viscosity
- 5. Iodine value
- 6. Saponification value
- 7. Acid values
- 8. Peroxide value
- 9. HPTLC of raw drugs and three samples of the Ghrita.

7.2 EXPERIMENTAL STUDY: / ANIMAL STUDY INVOLVES

- The three samples of prepared medicine will be orally fed to selected groups of Albino rats and the effect on memory will be analyzed. The study will be carried out at SDM Research Centre, Udupi.
- **METHODS:**
- Morris water maze method¹⁹
- The study will be conducted in 3 groups.
- 1st group – Brahmi ghrita prepared in 3 days is administered orally
- 2nd group – Go ghrita will be administered orally
- 3rd group - Control group
- 6 albino rats in each group will be taken respectively.
- Drug will be administered to albino rats for 7 days. On 8th day subjected for Morris water maze test. Dose of the animal will be calculating using the formula= Human dose \times 0.018

- **Inclusion criteria:**
 - 1) Weight range 120gms to 140gms
 - 2) Healthy albino rats of either sex.
- **Exclusive criteria:**
 - 1) Unhealthy albino rats
 - 2) Weight range below 120gms and above 140gms
- **Assessment criteria:**
 - The ability of rats to learn and remember the location of hidden platform located in a pre defined quadrant will be tested for 5 consecutive days. Rats that fail to reach the visible platform will be excluded from the analysis.
 - Daily escape latencies to the hidden platform as well as percent time spent and distance travelled in the target quadrant during the probe trial will be recorded.
 - The number of trails required for the establishment of memory in test drug group and control group are noted. By this data comparative effect will be assessed.

DIAGNOSTIC STUDY

ROGA NIDANA SYNOPSIS

A STUDY ON THE ANALYSIS OF THE ETIOLOGICAL FACTORS OF VATAJA AND VATAKAPAHAJA GRIDHRASI [SCIATICA]

By
Vaishnav
Guide
Dr Usha KS

- Patients of both Vataja and Vatakaphaja Gridhrasi will be selected from the IPD & OPD.
- **DIAGNOSTIC CRITERIA**
- Symptomatology mentioned for Vataja and Vatakaphaja Gridhrasi / X ray findings of lumbar region AP and LATERAL view.
- **INCLUSION CRITERIA**
- Patients of either sex / 16- 70 years
- Patients suffering only from vataja and vatakaphaja Gridhrasi will be selected.
- **EXCLUSION CRITERIA**
- Kati shoola, Kalli, Kanja, Pangu, Gudagatavata, Khalaya ganja, Urustambha

- 30 Diagnosed case of Gridhrasi in the age group of 16-70 years will be questioned for the etiological factors in which they indulged.
- **7.3) LABORATORY INVESTIGATION:**
- X-ray LS spine
- Blood routine examination.

Clinical Study

KAUMARABHRITYA SYNOPSIS

A CLINICAL EVALUATION ON THE EFFECT OF SVARNAMRITA PRASHANA ON GROWTH AND DEVELOPMENT IN CHILDREN

By

DR.NABISAB D. KAMATANUR

Guide

Dr Sudhakar Pawar

Objectives

- 1. A clinical efficiency of *Svaranamrita Prashana* in growth and development on the basis of DASII (Developmental Assessment Scale for Indian Infants)
- 2. To assess the efficacy of *Svarnamrita prashana* in preventing recurrent infections.
- 3. To assess the efficacy of *svarnamrita prashana* in improving overall general health of the child.

Source of Data

- 40 Healthy children freshly registered for *Svarnamrita Prashana* camp being conducted every month on the day of Pushya Nakshtra in S.D.M C.A.&H, Hassan will be selected.
- Parents willing to administer *Svaranamrita Prashana* to their children attending *Kaumarabhritya* immunization clinic at S.D.M CA&H, Hassan will also be selected.

Design

- **7.2 DIAGNOSTIC CRITERIA:-**Healthy child volunteer.
- **7.3 INCLUSION CRITERIA:-**
 - 1. Healthy children of age group of below 24 months / irrespective of sex, religion, socio economic status.
- **7.4 EXCLUSION CRITERIA:**
 - Children suffering any systemic illnesses.
 - Diagnosed cases of development delay.
 - Those children who undergoing *Svarnamrita Prashana*.
 - Parents not willing to participate in study and sign the consent form.

- **7.5 SAMPLING METHOD – 2 groups**

Group A- *Svarnamrita Prashana*

- 20 Children in study group will receive *Svarnamrita Prashana* 200mg (1mg gold/dose) once daily in morning on empty stomach for a period of 3months.

Group B- Placebo group

- 20 Children in placebo group will receive mixture of starch with *Madhu* 200mg similarly as study group.
- After completion of study children will followed for a period of one month

- **7.9 ASSESSMENT CRITERIA:**
- Assessment of growth and development using DEVELOPMENTAL ASSESSMENT SCALE FOR INDIAN INFANTS (DASII)
- Growth assessment using Anthropometry (body weight, length, head circumference, chest circumference, mid arm circumference, mid leg circumference)
- Measures of morbidity
- Complete blood count

KAYACHIKITSA SYNOPSIS

**A COMPARATIVE CLINICAL STUDY
ON
PATHYADI GUTIKA & DHATHRI LOHA
IN THE MANAGEMENT OF
PANDU WSR
IRON DEFICIENCY ANAEMIA**

By

DR. SREERAG N P

Guide

DR. LAKSHMIPRASAD L JADHAV

- **AIMS AND OBJECTIVES**
- To evaluate the individual effect of Pathyadi Gutika and Dhatri Loha in Pandu Roga
- To evaluate efficacy of Pathyadi Gutika in comparison to Dhatri Loha especially in improving haemoglobin percentage in Iron deficiency anemia.

- **Diagnostic criteria**
- Clinical signs and symptoms of Pandu Roga / Iron deficiency anemia.
- **Inclusion criteria**
- Patients with Hb% within the range of 7 to 11 gm/dl / either sex / 16 – 60 years
- **Exclusion criteria**
- Patients with h/O other systemic diseases like diabetes mellitus and hypertension / history of congenital disorders related with haemopoetic system like sickle cell anemia, leukemia, hemophilia / any infectious diseases like malaria / gastro intestinal bleeding / Pregnant ladies

- **GROUP A** :
- 30 patients of Pandu will be administered with Pathyadi Gutika- 2 tablets (1 tablet-250 mg) twice daily, with a glass of Takra, half an hour before food X 2 months
- **GROUP B** :
- 30 patients X Dhatri Loha- 1 tablets (1 tablet-500 mg) twice daily, along with 1 teaspoon of honey, half an hour before food X 2 months.

MANAS ROGA SYNOPSIS

- **A CLINICAL STUDY TO EVALUATE
THE EFFICACY OF
SARASVATA TABLET ON
MEDHA AND ACADEMIC
PERFORMANCE
IN SCHOOL GOING CHILDREN**

- By
 - DR. THEJASWINI H.J
 - GUIDE
 - DR. NARAYANA PRAKASH .B

- **DIAGNOSTIC CRITERIA:**
- Diagnosis will be made on the basis of Academic performance using school progress records followed by assessment of Medha.
- **INCLUSION CRITERIA:**
- Students of either sex, aged between 13-15 years studying 8th and 9th standards regularly attending the classes with poor academic performance studying in various normal schools in and around Hassan, Karnataka.
- **EXCLUSION CRITERIA:**
- Students with learning disabilities / with mental retardation.
- Students with ADHD./ Students with developmental disorders.
- Students with psychiatric illness like depression, anxiety etc.
- Students with personality disorders. / Students with Chronic systemic illness.

- **Treatment**
- 30 students full filling the inclusion criteria, after the initial screening for Medha will be selected for the study. The details will be noted in the specially designed clinical Proforma and Sarasvata tablet will be administered in the dosage of 2(250mg each) tablets twice daily in the morning, and night after food, for a period of 3 months.
- Children will be reviewed once in a month

PANCHAKARMA SYNOPSIS

EFFECT OF
KSHEERA VAITARANA KALA BASTI
ADMINISTERED IN MODIFIED
SCHEDULE
IN THE MANAGEMENT OF
VATAJA GRIDHRASI

By

Dr. ARYAN S NAMBOODIRI

Guide

Dr. Aswini Kumar M

OBJECTIVE

- To evaluate the efficacy of Ksheera VaitharanaBasti as Kala Basti (modified schedule) in management of Vataja Gridhrasi

- **(a) DIAGNOSTIC CRITERIA**
- Patient having pain in the course of sciatic nerve / Pain usually radiates down to the legs / Difficulty in walking / Positive SLR / X ray to confirm the lesion in vertebrae
- **(b) INCLUSION CRITERIA**
- 18 to 60 years / who do not need surgical procedures / indicated for Basti Karma.
- **(c) EXCLUSION CRITERIA**
- from fractures of pelvis and femur / symptoms due to trauma / other systemic disorders.

- All the patients will be given Ksheera Vaitharana Basti for 10 days in modified Kala Basti schedule as follows:

1 st day	2 nd day	3 rd day	4 th day	5 th day	6 th day	7 th day	8 th day	9 th day	10 th day
A	N	N	N	N	N	N	A	A	A
	A	A	A	A	A	A			

- **Nirooha Basti Poorva Karma:**
- Patient will be asked to be on empty stomach. Sthanika Abhyanga with Murchita Tila Taila and Nadi Sweda will be done on the lower abdomen, back and thighs of the patient.

PRASUTI TANTRA SYNOPSIS

CLINICAL MANAGEMENT OF UDAVARTINI YONIVYAPAD BY SUKUMARAGRITHA WSR TO PRIMARY DYSMENORRHEA

- By
- Udayakala
- Guide
- **DR. VISWESH.B.N**

- It is a single group exploratory study of 30 patients suffering from Udavartini Yonivyapad will be selected.
- Selected patients will be administered Sukumaragrita orally. 15ml once in the morning before the food with warm water or warm milk.
- The duration of treatment will be for one month, starting from one month before Last Menstrual Period & follow-up for the next two menstrual cycle.
- The parameters of signs and symptoms will be scored on the basis of standard method of statistical analysis.

SHALAKYA SYNOPSIS

EFFECT OF VIMALANJANA IN KAPHAJA TIMIRA WSR TO SENILE IMMATURE CATARACT

- **BY**
- **Dr Praveen Balakrishnan**

- 30 patients / 40-70 years / visual acuity 6/12 or less / Kaphaja Timira
- Treatment
- Vimalanjana in affected eye one drop twice daily for 60 consecutive days.

SHALYA

SYNOPSIS

Treatment

- 30 patients of Mutrashmari will be treated with Mulaka Kshara.
- Mulaka Kshara will be given to the patient for 21 days in a dose of 1gm,⁶ twice a day in divided dose after food with 10ml of water.

EFFECT OF JATYADI TAILA VRANA BASTI IN THE MANAGEMENT OF DUSHTA VRANA – A HISTOPATHOLOGICAL STUDY

- By
- Dr. UMMER FAROOQUE.V.V
- Guide
- Dr. P HEMANTHA KUMAR

- Diagnosis will be made on the basis of Lakshanas of Dushta Vrana
- **INCLUSION CRITERIA:**
- Patients suffering from Dushta Vrana .
- Dushta Vrana within size of 5x5 cm (length x breadth)
-
- **EXCLUSION CRITERIA:**
- Patients with disorders like Leprosy, Tuberculosis, Malignancy, HIV, HbsAg are excluded.
-

- **PLAN OF STUDY:**
- 40 patients of Dushta Vrana will be randomly categorized into 2 groups, of each comprising of 20 patients.
- **Povidone Iodine Group (PI Group):** The patients of this group will be applied by Betadine, once in a day and properly bandaged. Next day the dressing will be changed and in this way it will be continued for 7 days.
- **Jatyadi Taila Vrana Basti Group(VB Group):** The patients will be given Vrana Basti by Jatyadi Taila, once in a day and proper dressing will be done. Vrana Basti will be continued for 7 days.

SWASTHAVRITTA SYNOPSIS

A CLINICAL STUDY ON EFFICACY OF YAVAMALAKA CHOORNA IN DYSLIPIDEMIA

By

DR. SANDESHA KUMAR

- **GUIDE**
- **DR. SHIVAKUMAR**

- **6.3 Objective of the study**
- To evaluate the efficacy of Yavamalaka Choorna in dyslipidaemia.
- To evaluate the efficacy of Shudda Guggulu in dyslipidaemia.
- To compare the efficacy of Yavamalaka Choorna and Shudda Guggulu in dyslipidaemia

- In dyslipidemic patients, 18-60 yrs, Either gender with no complications will be included
- **Concomitant medication**
- Known lipid-lowering drugs like statins or fibrates will be stopped during the study.

- **Group A:** A group of 20 Subjects will be given with Yavaamalaka Choorna in a dosage of 6gm twice daily with warm water before half an hour of food for 2 months.
- **Group B:** A group of 20 Subjects will be administered with Shuddha Guggulu Vati in the dosage of 3gm BID with warm water as Anupana before food.
- **INVESTIGATION :** lipid profile

PRACTICALLY, STEPS TO BE FOLLOWED DURING SYNOPSIS PREPARATION

- a. Prepare atleast 20 summaries of thesis / research works on major areas of your specialities
- Pl refer to format provided

Format for Preparation of Summary of a Thesis / Disseration

- **A. First note down :**
- **1. Title of thesis :**
 - Name of author,
 - Department in which work is carried out
 - Institution
 - University :
 - Year of submission :
- **2. Read introduction which will brief about need for the study (or it will define problem). Jot down “need for the study” in 6-8 sentences.**
- **What is the problem that made scholar to take up the work? What is hypothesis?**

B. Method to be followed while summarizing the Thesis :

Directly go to Experimental/ Applied/Clinical study section of thesis

Note down following items:

- **Objectives**
- **Material and Methods :**
- **Source of Data :** Place where work is conducted (population)
- **Diagnostic Criteria and also inclusion and exclusion criteria (on what basis they included and excluded subject/animals/ tests/patients into /from study)**
- **Grouping including procedure/treatment plan which includes medicine or procedure followed, dose, duration, form of medicine, Anupana, diet restriction advised.**

Grouping :

- 1 or 2 or 3 groups
- If one group : it will be pre and post test design
- if two group : it is called as controlled. One group would be trial group and other would be known medicine or placebo like that...
- What is sample size and subjects/animals/patients in each group?
- Random allocation is followed or not. If yes, what method?

Treatment / Procedure Plan :

Note down following points

- Medicine /procedure : if drug, Its ingredients, botanical name, part used, proportion, form of medicine (tablet, syrup, Kashaya etc.), Package (ex : tablet 500 mg, Kashaya 200 ml bottle)
- If procedure, exact method (preoperative, operative and postoperative) followed to be noted. Note down if any medicine is used. If so, details of medicine as mentioned above.
- Reference or source from where medicine / procedure selected. Whether source of raw drugs mentioned? whether raw drugs authenticated? Where medicine is prepared. whether pharmacy is GMP certified?

Dosage Duration, anupana and Pathyapathya:

- how much procedure /medicine / day in divided doses along with what ? and for how many days? (ex : 2 tablets (each 500 mg) twice daily (total 4 tablets means $2 \text{ tabs} \times 2 = 4$ tablets - 2gm /day) along with Ushnodaka for 30 days)
- Whether any Pathya and Apathya advised during treatment / procedure to be noted.

Assessment Criteria :

- Assessment of effect of treatment / procedure
- Usually scale / lab test / specific test will be used to assess the effect of treatment / procedure at regular interval.

Statistical methods followed

- Usually “Student “t” test to assess before and after treatment effect within one group
- Unpaired “t” test to assess before and after treatment effect between two group
- If 3 groups, usually one way ANOVA test will be used.
- otherwise Mann-Whitney Signed rank test, Chi-square test / Make out which test is followed.

Start preparing brief 2 page synopsis..

- e. Once you have identified at least 10 topics / problems, start preparing brief 2 page synopsis or protocol (Annexure-I) of all the topics you have identified, which will give outline about each.
- This is the right time to approach your guide about the synopsis.
- So guide will give his input, do corrections and give his /her suggestions on each topic you proposed to carry out.

Start filling up Synopsis format prescribed by RGUHS, Bangalore.....

- f. Once your brief protocol and title are finalized. start filling up Synopsis format prescribed by RGUHS, Bangalore.

IMPORTANT POINTS TO PONDER BEFORE YOU JUMP FOR FINALIZING SYNOPSIS

- **Availability of patients / subjects / animals / facility :** (make a survey of OPD register and do a pilot study about feasibility. Because sample size depends upon prevalence of disease)
- **Check the Availability of drug :**
- **Budget for Medicine**
- Budget for procuring raw medicine / powdering / cost of preparation of medicine / cost of packaging (Contact RSBK Dept or SDM Pharmacy, Udupi)
- **Budget for laboratory investigations :**
- Cost of lab investigations OPD basis / IPD basis
- Check whether test / reagent is available, If not done at college, where it is available? what is approximate cost? try to get quotation.

OUTLINE FOR PREPARATION OF BUDGET :

Budget SHOULD BE calculated

Sl.	Item	Rs.
1.	Cost of Medicine Preparation	
2.	Cost of Lab investigations /Animal / experimental/analytical study	
3.	Cost for preparation of Thesis including photos	
4.	Cost for proforma / stationaries	
5.	Travelling cost	
6.	Statistician charges in needed	
	Total	

FINALLY !

- **Whether research is ethical ? : Yes / No. If no, what are issues you are facing?**
- **Whether study is feasible ? Yes /No : If no, what are issues regarding drug or budget or facility?**
- **Whether work is publishable?**
- **If pilot study is needed? If yes, when your are planning for the same. What are requirements and budget?**

Thank
you!