UNIVERSITY OF JAMMU JAMMU & KASHMIR



COMPLETE PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

SYNOPSIS BY

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TITLE OF THE SYNOPSIS

"A RANDOMIZED COMPARATIVE STUDY ON THE ROLE OF NAVKARSHIKA KWATHA AND VARYADI KASHAYA IN THE MANAGEMENT OF VATARAKTA WITH SPECIAL REFERENCE TO GOUTY ARTHRITIS"

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This is to certify that we will supervise the thesis/research work of **DR. SAMBHAVI PURI** 1st Year M.D. student, the synopsis of which titled as "A RANDOMIZED COMPARATIVE STUDY ON THE ROLE OF NAVKARSHIKA KWATHA AND VARYADI KASHAYA IN THE MANAGEMENT OF VATARAKTA WITH SPECIAL REFERENCE TO GOUTY ARTHRITIS" is enclosed here with, for the research work to be done during the second and third year of M.D Kayachiktisa. The Synopsis submitted is selected and prepared under our guidance.

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INTRODUCTION

Ayurveda is an ancient medical and health care system which is not only manages chronic diseases but maintain the health of the human being i.e., retain the body health also. Ayurveda tell us how to live for healthy life by following the Dinacharya. The statement, "The inequalities of basic constituents in the body are the root cause for different diseases" is the fundamental principle of the Ayurveda, which indicate the control of different fundamental elements in the body (Sharira) is the sign of good health and free from diseases. It is accepted and used worldwide. Moreover, new research and revalidation of old Ayurvedic principles and concepts mentioned in Ayurvedic classics are reestablishing worldwide. Nowadays human beings are more vulnerable to metabolic disorders due to their faulty dietary habits and sedimentary life style. These disorders may be causing functional impairment or crippling diseases. Some of these disorders produced by conjugation of Vitiated Vata and Rakta generated multiple health illnesses and most important of them is Vatarakta¹.

Vatarakta is a disease explained in Ayurveda involving Vatadosha imbalance affecting Raktadhatu. Acharya Charaka has described that before the planning of treatment, the correct diagnosis of a disease is very much essential². There are five means of diagnosis (Nidana Panchak) namely -Nidana(cause or etiology), PurvaRoopa(prodromal symptoms or premonitory symptoms), Roopa(specific sign and symptoms or clinical features), Upashaya(relieving and aggravating factors), Samprapti(pathogenesis).

These five basics collectively help in making the accurate diagnosis. The physician can diagnosis the disease at an earlier stage by using the concept of *Nidana Panchak*, thereby manage the disease and prevent further complications.

The classical signs and symptoms of *Vatarakta* resemble the clinical features of Gouty arthritis, hence *Vatarakta* can be correlated with gouty arthritis due to a number of similarities. The aetiological factors responsible for gouty arthritis are quite similar with *Vatarakta*. In conventional science it is known as King's disease and in *Ayurveda*, it is known as *Adhya vata*. *Vatarakta* usually starts from the big toe and gradually involves other joints. Gout usually affects one joint in the beginning (Monoarticular), usually the big toe. Gout is a systemic metabolic disease caused by precipitation of Monosodium urate monohydrate (MSUM) crystals in and around synovial joints³. The clinical progression of Gout can lead to Gouty arthritis, characterized by painful swelling and tenderness, usually of the great toe and first metatarsophalangeal joint⁴.

NEED FOR THE STUDY

Prevalence of Gout is progressively increasing in affluent societies and in developing countries like India with overall prevalence of 2- 26/1000 and incidence from 0.2 to 3.5 per 1000⁵. The prevalence increases with age and usually affects males, and is the most common cause of inflammatory Arthritis in men over the age of 40 years. Symptomatic treatment of Gout in modern science includes use of NSAIDS, colchicines, corticosteroids which have numerous adverse effects. Corticosteroids cause Uricosuria, its use in Chronic Gout is not recommended. Thus there is a need for a safe and effective management of this disease through the application of *Ayurvedic* treatment principles in *VataRakta*.

Varyadi kashaya⁶ has been mentioned in Sahasrayogam, Pratham Prakarana (Kashaya yoga) and Navkarshika Kwatha⁹ mentioned in Chakradatta in Vatrakta Chikitsa Adhyaya 23/21.

Taking the above background into consideration, it was thought worth while to evaluate the efficacy of oral administration of *Varyadi kashaya*⁶ and *Navkarshika Kwatha*⁹ in the management of *Vatarakta* with special refrence to Gouty Arthritis.

PREVIOUS WORKS DONE

- 1. Government Ayurvedic College and Hospital Jalukbari, Guwahati, Assam –Dr. Gunjana Bhardwaj (2023)- A clinical trial to study the effectiveness of *Laghumanjishtaadi Kwath* in the management of *vatarakta* (Gout).
- 2. Government Ayurvedic College Kadamkuan, Patna, Bihar Dr.Sushil Kumar Jha (2023) A clinical study on the efficacy of *Talmakhana amrita kwath* in *vatarakta* w.s.r to gouty arthritis.
- 3. Banaras Hindu University ,Varanasi Dr Tanmay Nigam (2023) A comparative clinical study of *Bodhivriksha kashaya Ghana vati* and Febuxostat in the cases of *vatarakta* vis a vis Gout.
- 4. Hon Shri Annasaheb Dange Ayurved Medical College and Post Graduate research center, Ashta ,Sangli Dr. Snehal Shivaji Kamble (2021) Study of *Guggul vatika and Kaishore guggulu in vatarakta*.
- 5. Parul Institute Of Ayurveda Dr.Shivangi Choube (2019)- A clinical study on the management of *vatarakta* w.s.r to Gout with *Navkarshika Ghana vati*.
- 6. Jammu Institute of Ayurveda and Research– Dr.Rakhi Khajuria (2013]-Clinical evaluation of *Suranjan and Amrita Satva* in the management of *Vatarakta*w.s.r to Hyperuricemia .
- 7. Jammu Institute of Ayurveda and Research—Dr.Nikhil Sharma (2012]-Clinical evaluation of *AshvathaTwakKwatha with Madhu* in the management of *Vatarakta* W.S.R to Gout.
- 8. International Journal Of Ayurvedic Medicine Vol 11 (3), 441-445 Evaluation of efficacy of *Navakarshik Kwath Ghan in Sheetpitta* with special reference to Urticaria.

AIMS AND OBJECTIVES OF THE STUDY

AIM

• To compare the efficacy of *Navkarshika Kwatha* and *Varyadi kashaya* in the management of *Vatarakta* with special reference to Gouty Arthritis.

OBJECTIVES

- 1. To conceptually analyze *Vatarakta* with special reference to Gouty Arthritis.
- 2. To evaluate the efficacy of *Navkarshika Kwatha* and *Varyadi kashaya* in the management of *Vatarakta* with special reference to Gouty Arthritis.
- 3. To compare the effect of *Navkarshika Kwatha* and *Varyadi kashaya* in *vatarakta* with special reference to Gouty Arthritis.

HYPOTHESIS:

\bullet NULL HYPOTHESIS (H₀):

- 1. There will be no significant effect of *Navkarshika Kwatha* in the management of *Vatarakta* with special reference to Gouty Arthritis.
- 2. There will be no significant effect of *Varyadi kashaya* in the management of *Vatarakta* with special reference to Gouty Arthritis.

\star <u>ALTERNATIVE HYPOTHESIS (H_A)</u>:

 $\mathbf{H_{A1}}$: There will be significant effect of *Navkarshika Kwatha* in the management of *Vatarakta* with special reference to Gouty Arthritis.

 \mathbf{H}_{A2} : There will be significant effect of *Varyadi kashaya* in the management of *Vatarakta* with special reference to Gouty Arthritis.

H_{A3}: There will be significant effect of *Navkarshika Kwatha* as compare to *Varyadi kashaya* in management of *Vatarakta* with special reference to Gouty Arthritis.

 $\mathbf{H_{A4}}$: There will be significant effect of *Varyadi kashaya* as compare to *Navkarshika Kwatha* in management of *vatarakta* with special reference to Gouty Arthritis.

REVIEW OF LITERATURE

DISEASE REVIEW:-

- *CharakaSamhita*: In *CharakaSamhita*, *ChikitsaSthana* 29th chapter, the complete picture of the disease starting from the etiology to the management is well elaborated.
- SushrutaSamhita: In SushrutaSamhita, Acharya Sushruta has explained in NidanaSthana 1thchapter and 5thchapter of the ChikitsaSthana.
- Ashtanga Sangreha: In Ashtang sangreha chikitsa sthana,24 chapter Vata shonitya chikitsa.
- AshtangaHridya: In Ashtang Hridya Chikitsa Sthan, 22 chapter Vata shonit chikitsa.
- Madhava Nidana (800 A.D): Madhavakar explains details of Vatarakta nidana, Samprapti, Purvarupa, Doshapradhanrupa, Updrava, Asadhyalakshana in 23 adhyaya.
- Chakradatta(1100A.D): Regarding treatment aspect Bahya and Abhyantara Chikitsa- kvatha, Churna, Ghrita, Tail, Guggulukalpa is explained in Vatrakta Chikitsa Adhyaya 23.
- Sharangadhara Samhita: Purvakhanda Saptam adhyaya explained details about Saptaprakara of Vatarakta as Vataja, Pittaja, Kapaja, Sannipataja, Samsargaja, RaktajaVatarakta. While explaining Niruha Basti, Vatarakta has been mentioned as one of the indications for Niruha Basti.
- BhavaPrakasha: Uttarardha 29 adhyaya Vatashonita explains all about -Nidana, Samprapti, Purvarupa, Rupa, Bheda and variety of Chikitsa.
- Bhaishajyaratnavali: In this text description about Samprapti, Bheda, Pathyapthyaand Chikitsa is available in Vatrakta Chikitsa Adhyaya 27.
- *GadaNigraha*: The detail description of the disease, *Vatarakta* with its *Chikitsa* has been mentioned in 20th chapter *Vataraktadhikar*.

❖ DRUG REVIEW:

The trial drug under consideration *Navkarshika Kwatha*⁹ contains Haritaki¹⁰, *Bibhitaki*¹¹, *Amalaki*¹², *Nimba*¹³, *Manjishta*¹⁴, *Vacha*¹⁵, *Katuki*¹⁶, *Guduchi*¹⁷, *Daruharidra*¹⁸.

<u>Table No. 1</u> Navkarshika Kwatha⁹ mentioned in Chakradatta in Vatrakta Chikitsa Adhyaya 23/21.

S No	INGREDIENT	LATIN NAME	RASA	GUNA	VIRYA	VIPAKA
1	Haritaki ¹⁰	Terminalia chebula	Panchrasa(lavan varjit)(Kashaya pradhan)	Laghu , Ruksha	Ushna	Madhura
2	Bibhitaki ¹¹	Terminalia bellirica	Kashaya	Laghu , Ruksha	Ushna	Madhura
3	Amalaki ¹²	Emblica officinalis	Panchrasa(Lavanara hita), Amlapradhana	Guru,Ruksha, Sheeta	Sheeta	Madhura
4	Nimba ¹³	Azadirachta indica	Tikta,Kashaya	Laghu	Sheeta	Katu
5	Manjishta ¹⁴	Rubia cordifolia	Tikta,Kashaya, Madhura	Guru, Ruksha	Ushna	Katu
6	Vacha ¹⁵	Acorus calamus	Katu, Tikta	Laghu, Teekshna	Ushna	Katu
7	Katuki ¹⁶	Picrorhiza kurroa	Tikta	Ruksha, Laghu	Sheeta	Katu
8	Guduchi ¹⁷	Tinospora cordifolia	Tikta,Kashaya	Laghu ,Snigdha	Ushna	Madhura
9	Daruharidra ¹⁸	Berberis aristata	Tikta,Kashaya	Laghu ,Ruksha	Ushna	Katu

Actions of Navkarshika Kwath⁹ -

S No	INGREDIENT	DOSHGHANTA	KARMA	PART USED	PROPORTION
1	Haritaki ¹⁰	Tridoshahara	Vedanasthapana, Deepan,Pachan, Anulomana, Mriduvirechak, shothahara,mutrala	Fruit	1 Part
2	Bibhitaki ¹¹	Tridoshahara	Shothahara, Vedanasthapana, Anulomana, Its ardhapakva phala is virechak	Fruit	1 Part
3	Amalaki ¹²	Tridoshahara	Dahaprashmana,Mutrala, Anulomana, Deepan	Fruit	1 Part
4	Nimba ¹³	Kaphapitta shamaka	Dahaprashmana, Aam Pachana	Leaves	1 Part
5	Manjishta ¹⁴	Kaphapitta shamaka	Shothahara,Raktashodak, Deepan,Pachan	Root	1 Part
6	Vacha ¹⁵	Kaphavata shamaka	Vedanasthapana, Shothahara,Deepan, Anulomana	Root	1 Part
7	Katuki ¹⁶	Kaphapitta shamaka	Deepan,Virechak, Dahaprashamana	Root	1 Part
8	Guduchi ¹⁷	Tridosh shamaka	Vedanasthapana, Anulomana , Raktashodak and Dahaprashamana	Stem	1 Part
9	Daruharidra ¹⁸	Kaphapittahara	Shothahara, Vedanasthapana, Deepan, Raktashodak, Pitta sarak	Root	1 Part

The trial drug under consideration Varyadi kshaya⁶ contains Shatavari¹⁹, Guduchi¹⁷.

S NO	INGREDIENT	LATIN NAME	RASA	GUNA	VIRYA	VIPAKA
1	Vari(Shatavari) ¹⁹	Asparagus racemosus	Madhura, Tikta	Guru, Snigdha	Sheeta	Madhura
2	Guduchi ¹⁷	Tinospora cordifolia	Tikta, Kashaya	Laghu ,Snigdha	Ushna	Madhura

Actions of Varyadi Kashaya⁶ -

S No	INGREDIENT	DOSHGHANTA	KARMA	PART	PROPORTION
				USED	
1	Vari(Shatavari) ¹⁹	Vatapitta shamak	Vedanasthapana, Mutrala	Tuber	1 Part
2	Guduchi ¹⁷	Tridosh shamaka	Vedanasthapana, Anulomana, Raktashodak and Dahaprashamana	Stem	1 Part

MATERIAL AND METHODS

1. Conceptual Study

Literary aspect of study will be collected from Classical *Ayurvedic* and contemporary text including the journals and website about the disease and drugs.

2. Clinical Study

The patients of either sex, suffering from "VATARAKTA" will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.

PLAN OF STUDY

- Clinical Study: For Clinical study, patient will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.
- Type of Study: Randomized, open labeled, Parallel group.
- **Level of Study :** O.P.D. & I.P.D. level.
- **Period of Study:** 18 months.

FOLLOW UP:

- Follow up(GroupA & Group B):- on 15th day, 30th day and 45th day
- **Drug free Follow up(GroupA & Group B)**:- on 45th day

SAMPLE SIZE

30 patients divided in 2 groups of 15 patients in each group.

***** Grouping:

GROUP	DRUG	NO. OF PATIENTS
GROUP A	Navkarshika Kwatha ⁹	15 patients
GROUP B	Varyadi Kashaya ⁶	15 patients

INCLUSION AND EXCLUSION CRITERIA

A. <u>INCLUSION CRITERIA</u>

- 1. Subjects aged between 25 to 60 years of either sex will be selected.
- 2. Subjects presenting with clinical features of *vatarakta* (gouty arthritis).
- 3. Serum Uric Acid:
 - More than 7.0mg/dl in Males.
 - More than 6.0mg/dl in Females.
- 4. Subjects willing to participate with written informed consent, which is conveyed in the language which the subject can understand.
- 5. Chronicity less than 2 years.

B. EXCLUSION CRITERIA

- 1. Subjects diagnosed with other inflammatory and degenerative joint diseases.
- 2. Subjects with history of trauma, fractured joint, surgical or diagnostic intervention with reference to the affected joint(s).
- 3. Subjects having any marked deformity.
- 4. Subjects with any uncontrolled systemic illness including DiabetesMellitus, Hypertension.
- 5. Pregnant and Lactating woman.
- 6. Chronicity more than 2 years.

DRUG SELECTION AND PREPARATION

✓ Collection of drugs :-

• Ingredients of trial drug *Navkarshika Kwatha*⁹ and *Varyadi kashaya*⁶ will be procured from the authentic sources, identified and approved by Department of *Dravya Guna*, Jammu Institute of Ayurveda and Research, Jammu.

✓ Preparation:-

> Trial Drugs :-

(1) Navkarshika Kwatha⁹

- The raw ingredients of the *Navkarshika Kwatha*⁹ will be taken in equal parts.
- Haritaki¹⁰, Bibhitaki¹¹, Amalaki¹², Nimba¹³, Manjishta¹⁴, Vacha¹⁵, Katuki¹⁶, Guduchi¹⁷, Daruharidra¹⁸ will be made into coarse powder in the pharmacy of Department of Rasa Shastra and Bhaishajya Kalpana, Jammu Institute of Ayurveda and Research, Jammu.

(2) Varyadi kashaya⁶

- The raw ingredients of a *Varyadi kashaya*⁶ will be taken in equal parts.
- Shatavari¹⁹, Guduchi¹⁷ will be made into coarse powder in the pharmacy of Department of Rasa Shastra and Bhaishajya Kalpana, Jammu Institute of Ayurveda and Research, Jammu.

METHODS OF DATA COLLECTION

Randomization: Randomization will be done by using randomization software from www.randomizer.org.

Sampling Technique:-

- Subjects will be randomized in two groups.
- A special Case Report Format (CRF) containing all the necessary details pertaining to the study will be prepared.
- Data obtained in the group will be recorded, tabulated and statistically analysed.

INTERVENTION

> Group A

- Yoga:- Navkarshika Kwatha⁹
- **Dosage :-** 48 ml twice a day before meals⁷
- **Duration :-** 30 days
- **Follow up :-** on 15th day, 30th day and 45th day
- **Drug free Follow up :-** on 45th day

> Group B

- Yoga :- Varyadi kashaya⁶
- **Dosage :-** 48 ml twice a day before meals⁷
- **Duration :-** 30 days
- **Follow up :-** on 15th day, 30th day and 45th day
- **Drug free Follow up :-** on 45th day

ASSESSMENT CRITERIA

For evaluating the efficacy of drugs, following parameters will be adopted before and after the completion of clinical trial.

SUBJECTIVE CRITERIA

- 1. Sandhishula
- 2. Daha
- 3. Sandhishotha
- 4. Sparshaasahatva
- 5. Vaivarnya

***** OBJECTIVE CRITERIA

- 1. Serum UricAcid levels
- 2. ESR

❖ SUBJECTIVE CRITERIA ASSESSMENT SCALE^{8,20}:-

SUBJECTIVE PARAMETER	PARAMETERS	SCALE
	No Pain	0
Sandhishula (Joint Pain) ²⁰	Mild Pain	1
	Moderate Pain	2
	Severe Pain	3
	Absent	0
Daha (Burning sensation) ⁸	Mild	1
	Moderate	2
	Severe	3
	No Swelling	0
Sandhishotha (Joint Swelling) ⁸	Swelling but not apparent	1
	Swelling obvious on lesser than 2 joints	2
	Swelling obvious on greater than 2 joints	3
Sparshaasahatva (Tenderness) ²⁰	None	0
	Mild	1
	Moderate	2
	Severe	3
Vaivarnya ²⁰	None	0
	Mild	1
	Moderate	2
	Severe	3

CRITERIA FOR OVERALL EFFECT OF THERAPY

The result will be categorized as :-

Complete Remission	100% relief in subjective and objective
	parameters
Marked Improvement	More than 76% Relief in subjective and
	objective parameters
Moderate Improvement	51%-75% Relief in subjective and objective
	parameter
Mild Improvement	26%-50% Relief in subjective and objective
	parameters
Unchanged	Result below 25% will be considered as
	unchanged

CONCLUSION

Conclusion will be made on the basis of observation which is done on subjective and objective parameters, result will be analysed statistically and discussed accordingly.

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