

**Synopsis of the thesis**

**Randomized open comparative study of efficacy of Lohatriphaala churna  
and Nishamalaki yoga in management of prameha**

**A SYNOPSIS**

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**In partial fulfillment for the award of the degree of**

**DOCTOR OF PHILOSOPHY**

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**2022-2023**

# **Title :- Randomized open comparative study of efficacy of Lohatriphaala churna and Nishamalaki yoga in management of prameha**

## **Introduction**

As humanity is having progress in material world we as a human are losing touch with the nature. We leads easy and comfortable life but it also giving rise to fast life style. It is cause of various metabolic mental and behavioral discords.

Increase in Stress disorders, cardiac problems, diabetes are result of such life style.

Prameha is caused by sedentary lifestyle. Heavy and junk food eating. Most of the population is having some of this error in their daily life.

As ayurved is ancient stream of knowledge. It tell not only about treatment of disease but correct way of life hence it is called as life science.

Prameha is now globally incident disease. Its prevalance rate in 1984 in india was 4.7% but in 2019 it has increased to 8.9%. it has doubled in last thirty years.

More and more people are suffering from this disease. At this rate soon india will become diabetes capital in the world.

Prameha vyadhi slowly affect all the dhatu producing dhatushaithilya.

It give rise to various other disorders.

So I have selected prameha for my thesis as it will impact more people and hope to improve their life by some degree.

## **Need of study**

Prameha vyadhi generally comes with various other updravas and disorders. It inconvenience day to day life of patient. For betterment of patient and to have option of healthy life again there required various approach to treatment of prameha.

## **Knowledge gap**

As due to high prevalance rate many researchers have worked on this disease. But as ir causes many physiological problems, various means of correction are required. With cure of disease correction of updravas is also necessary. Hence to provide more data for further understanding the presentation of this topic for research purpose.

Aim :- To clinically assess efficacy of Lohatriphala churna and Nishaamalki yoga in prameha .

Objectives :-

Primary Objective:

To assess effect of both drugs by noting down changes in various parameters that are considered for study.

Secondary Objective :

1. To compare and analyze the effect of Lohatriphaladi churna and Nishaamaki yoga statistically to meet the aim of study
2. To study the etiopathogenesis of Prameha in Ayurvedic and modern aspect.
3. Any new theoretical and concept, if found will be noted down.

**Primary Research question :-**

Is Lohatriphala churna is more effective than Nishaaamlki yoga?

**Null Hypothesis (Ho) :-** There is no significant difference in efficacy of Lohatriphadi Churna and Nishaamlki yga in the management of prameha. .

**Alternate Hypothesis (H1):-** There is significant difference in efficacy of Lohatriphadi Churna and Nishaamlki yga in the management of prameha.

## REVIEW OF LITERATURE

- Detailed review regarding the disease and the drugs will be taken from Vedic Literatures, classical literatures, contemporary Ayurvedic literatures, modern literatures, journals and internet sources.
- Detailed description about the disease is given in Charaka Samhita Sutrasthana 21st Chapter, Susrutha Samhita Sutrasthana 15th chapter, Ashtangsamgraha Sutrasthana.
- Yogratanakar 40<sup>th</sup> chapter medorogadhikar and bhavprakash madyakhand 39<sup>th</sup> chapter sthauyadhikar also mentioned details about medoroga.
- The Drug used for clinical assessment in the present research work is taken from Yog Ratnakar Medaorogaa Adhikar.
- Description of Obesity, causes and complications from the contemporary science.

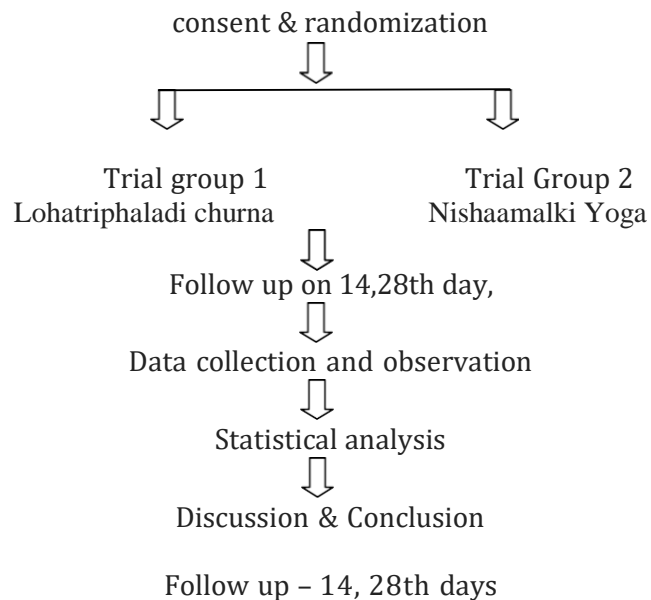
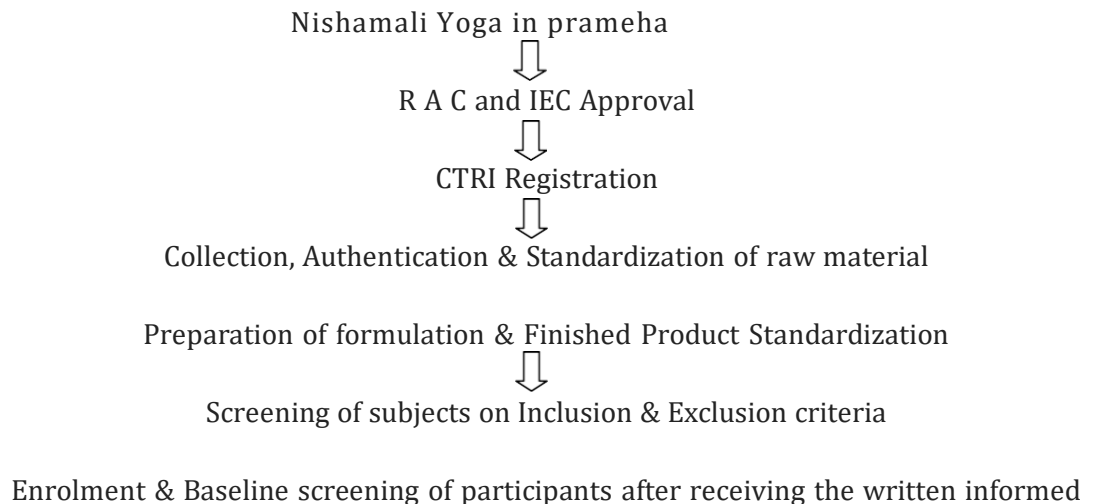
## 3.2 REVIEW OF PREVIOUS WORK DONE

1. Baghel A.S. – Studies on concept of dosh dushya samyoga vaishistya w.s.r.t. mutra pariksha in prameha roga.—1994- Baghel – ch 2-138.
2. Nagaraja T. N. – study of Naga bhasm w.s.r. t.its effect on prameha- 1988-Baghel-ch 4-223.

3. Jain A.K.- correlation of prameha with diabetes malitus and its management with certain indigenous drugs w.s.r.t. to prakruti -1983 –baghel ch 16-14.
4. Ram Krishna – swarna vang ka nirman evam prameha par Adhyayan-1990- Baghel ch 18-12
5. Chuhan K-medo dushti evam iska vrikka karm par prabhav visheshtah prameh ke sandarbhb men – 1990- Baghel –ch 14-26.

## Study design

Comparative clinical trial of Lhatriphaladi churna and



**Material & Method :-**

**Material :-**

**Drug Review :-**

**A) Lohatriphaladi Churna** - It contains Lohabhasm, triphala churna Haritaki churna in

same proportion. Take all ingredients fine powder in same proportion and mix it thoroughly.

**B) Nishaamlakki yoga-** It contains haridra churna and amalki phala swaras. Take haridra churna and give amalki phal swaraas bhavna to make 500 mg tablets.

**1) Lohabhasm-** it is tasteless, odorless, dark brown powder. It is easily absorbable, strengthen body, rug jara vinashanam.

**2) Aamalaki-(Emblica officinalis)-** It has Lavan varjit panch ras ,Madhur vipak,sheet virya. It is Agni Deepak, aam pachak, anulomak .It is kledaghna, dhaatu shodhak. It digest dhaatugat dosh, throw them out. And used as vayasthapak.

**3) Haritaki -(Terminalia Chebula)-** It has Lavan varjit kashaya ras Pradhan ras, Madhura vipak and ushna virya. It is digestive ,Agni Deepak, aam pachak, kledaghna ,lekhan on Meda dhaatu. It removes strotorodh ,so used as rasayan.

**4) Bibhitak -(Terminalia Belerica)-** It has kashaya ras, madhura vipak, ushn virya. It is Deepak, pachak, anulomak ,dushta kafaghna. It is khafapittaghna. It is shothahar.

**5) Haridra - (Curcuma longa)-** it has tikta madhur ras, katu vipak, ushna virya. It is kaphaghna, pittashamak and kledaghna.

## **Methods :-**

### **Trial design:-**

1. Select 100 patients from OPD having prameha in each group.
2. They are separated randomly in 2 groups namely A & B.
3. Odd number patient like 1, 3, 5 will be added in group A and even number patients like 2,4,6 will be added group B.
4. Lohatriphaladi churna 3gm given to group A. Dose is 3gm after food with honey two times a day.
5. Nishamalki yoga given to group B. Dose is 2tablets 500mg after meal two times a day.
6. Record subjective & objective criteria on day 0.
7. Continue the Medicines up to 28 days.
8. Record subjective & objective criteria at 14, 28 days.
9. We will collect, segregate & analyze the data afterword's.
10. Will draw conclusion after use of proper statistical test

## Sample Size:-

Formula for sample size calculation –

$$N = Z^2P \times (1-P) / d^2$$

Z = 1.96 (for 5% level of significance)

P = 0.1 (P is percentage of prevalence in India is 8.9)

d = 0.05 (tolerate margin of error 5%)

$$\begin{aligned} \text{Hence sample size } n &= (1.96)^2 \times 0.08(1-0.08)/(0.05)^2 \\ &= 0.3319/0.0025 \\ &= 132 \end{aligned}$$

Therefore I will select total 100 patients with either sex in each group

### Sampling technique:-

- Screening of patients of prameha will be using as a purposive sampling method who meets the inclusion criteria until desired sample size is achieved.
- Patients of prameha will be randomly selected in OPD and IPD of concern Institute irrespective of gender economic status, religion and occupation.
- Assessment will be done along with pre-post treatment follow up and data collection.
- Written informed valid consent of the patient will be taken prior to the clinical study.

### Method of selection of study subject:

Inclusion criteria:-

- Diagnosed diabetes patients
- Male & Female patients having age between 35 to 60 yrs.
- Patients with fasting blood glucose 126mg/dl – 226mg/dl  
Pp blood glucose 200mg/dl-300mg/dl
- Patients taking metformin(OHA) as regular treatment
- Patients willing to participate in study

Exclusion criteria:-

- Patients having age <35 and >60 years
- Patients having chronic diseases of Kidney, Liver, Heart & Brain.
- Patients having other illness which might be interfering lifestyle and food habits.
- Patients taking insulin or any other OHA other than metformin
- Patients not willing to participate in study.

Criteria for withdrawal:-

- Left against medical advice
- Development of complication due to presenting illness or otherwise.
- Aggravation of symptoms.
- Any other pronounced side effect caused by medicine.

Interventional definitions:

Sr. no	Group	No. of patients	Treatment
1	A	59	Lohatriphaladi churna
2	B	59	Nishaamalki Yoga

	Group A Lohatriphaladi churna	Group B nishaamlaki yoga
DOSE	3 gm churana	2 tablets (500mg each)
TIME	Twice a day Bhojan pashchat(after lunch and dinner)	Twice a day Bhojan pashchat (after lunch and dinner)
ROUTE	Orally	Orally
DURATION	28 day	28 day
FOLLOW UP	Clinical follow up on 14 <sup>th</sup> and 28 <sup>th</sup> day	Clinical follow up on 14 <sup>th</sup> and 28 <sup>th</sup> day

### **Subjective Criteria:-**

Changes in the subjective parameters (signs & symptoms) of prameha will be assessed by Gradation method. Symptoms are arbitrarily graded in 4 grades (0-3) on the basis of severity.

1) Prabut mutrata

Grade 0 4-6 times per day

Grade 1- 7-9 times per day

Grade 2 10-12 times per day

Grade 3 >13 times per day

2) Pipasadhikya

Grade 0 8-10 glass per day

Grade 1 10-15 glass per day

Grade 2 15-0 glass per day

Grade 3 unable to have sound sleep due to thirst

3) Karpad daha

Grade 0 absent

Grade 1 occasional

Grade 2 continuous

Grade 3 continuous and required medication

4) Karapad suptata

Grade 0 absent

Grade 1 occasional

Grade 2 continues

Grade 3 continues and required medication

5) Kshudhadikya

Grade 0 2chapati/meal

Grade 1 3-4 chapati/meal

Grade 2 4-5 chapati/meal

Grade 3 >5 chapati/meal

### **Objective Criteria:-**

**Bsl F**

**Bsl PP**



### Overall assessment criteria

Complete remission 100% relief in sign and symptoms

Marked improvement >75%-<100% relief in sign and symptoms

Moderate improvement >50% - <75% relief in sign and symptoms

Mild improvement >25% - 50% relief in sign and symptoms

No improvement >25% relief in sign and symptoms

### Data collection tool

Case record form and clinical efficacy of treatment will be observed and recorded.

### Data analysis plan

The collected data will be properly analysed 5% level of significance whenever necessary

For subjective data Mann Whitney U test

For objective data unpaired t test

### Observation and results

Clinical efficacy of treatment will be observed and recorded. Result will be drawn using statistical data. Accordingly statistical test will be applied.

### Discussion:

It shall be based on observation statistical analysis.

### Summary

All experimental work shall be summarized systematically.

### Reference style Vancouver:

1. Dr K. Nishtewar, Dr. R Vidyanath – rajmartanda (Nanavidhayogsangrah), Chukhamba Orientalia publication, edition 2009, page no -373.
2. Dr. M.S. Baghel – Research in ayurveda, Mridu Ayurvedic Publication, edition 1997
3. Prof A.P. Deshpande, Pro.R.R Jawalgekar- Dravyagun Vigyan, Anmol Prakashan, Edition 2008, page no- 655, 672, 452, 460.
4. Dr. sidhinandan Mishra- Ayurvediy Rasashastra, chukhamba Orientalia, Edition- 2006, page no-460.
5. Role of somvalk kashay asthapan basti in prameha w. s. r. to diabetis mellitus. Year :2018. Volume:5. Issue: 6. Page no- 1971-1987 Arti Mali, Sandip Mali, Vipul Gaurav, ISSN 2393-9583(p)/2393-9591(O)
6. Sample size- <http://www.surveysystem.com/sample-size-formula>



## CASE RECORD FORM

**“A parallel comparative clinical trial of Medoghna action of Guduchyadi  
Churna with trifala churna”**

### GENERAL INFORMATION

OPD NO. :

Date:

Name :

Sex:

Age :

Height:

weight:

Address :

Phone No.:

Occupation:

Marital Status :

VEDANA VISHESH (Chief Complaints)

VARTAMANA VYĀDHI VRUTTANT ( History of Present illness )

PURVOTPĀNNA VYĀDHI VRUTTANT (History of Pāst illness)

KULVRUTTANT( Family History )

Matruj :

Pitruj :

Swakul:

MEDICINE ALLERGY

PREVIOUS MEDICATION

## RUGNA PARIKSHANA

- 1) Prakṛuti
- 2) Sara (Saptadhatu) :
- 3) Samhanan :
- 4) Pramana (Kṛush, Madhyam, Sthuolya ) :
- 5) Vaya :
- 6) Satmya :
- 7) Satva :
- 8) Āhara śhākti :
- 9) Vyāyama śhākti :
- 10) Desh :
- 11) Kāl :
- 12) Bal :

## VITAL EXAMINATION

BP:	MmHg	R. Rate	/Min	Temp.	<sup>0</sup> F
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## ASHTAVIDHADI PARIKASHAN

Nadi	
Mala	
Mutra	
Jivha	
Shabda	
Sparsha	
Druka	
Aakruti	
Kshudha	
Nidra	

Kostha			
Agni	Jatharagni	Panchabhautik agni	Dhatu agni

### SROTASA PARIKSHANA

1) Medaovaha:

2) Rasavaha:

3) Swedovaha :

4) Udakvaha:

5) Manovaha :

6) Mansavaha:

7) Pranavaha:

8) Asthivaha:

9) Majjavaha:

10) Shukravaha:

11) Purishavaha :

12) Annavaha:

13) Ārtavvaha :

14) Raktavaha:

### FOLLOW UP MONITORING

Lakshana	Before Treatment	After Treatment		
	0	14	28	
Prabhut mutrata				
pipasdhikyata				
Karapad daha				
Karapad suptata				

khudhadhikya			
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#### OBJECTIVE PARAMETERS

	Before Treatment	After Treatment	
	0	14	28
BSL F			
BSL PP			

#### HETU

Aaharaj :

Viharaj :

Anya :

#### ROGA PARIKSHA

- Dosha
- Dushya
- Srotodusti
- Rog Marg

➤ Chikitsa

➤ Pathya/Apathya

Result                      Markedly improved/Improved/ Unchanged

Date: .....

Signature of the investigator: .....

Name of the Investigator: .....

**Signature of Student**

**Signature of Guide**

## INFORMED CONSENT

I, Mr. / Mrs. \_\_\_\_\_ hereby giving my consent to undergo examination and treatment in the Research project, Randomized open comparative study of efficacy of Lohatriphaala churna and Nishamalaki yoga in management of prameha. I have been fully informed about the nature, duration, dose of the said treatment. I am ready for the full treatment and follow-up. I have given my consent in complete consciousness and without being under any pressure.

**Date:**

**Sign/ Thumb:**

**Place:**

**Name of Patient:**

रुग्ण नाव -

डॉक्टरांनी मला माझ्या आजाराची संपूर्ण माहिती व कल्पना दिली आहे. मला डॉक्टरांनी कराव्या तपासण्या, औषधोपचार, त्यांचे परिमाण व संभाव्य दुष्परिणाम किंवा अकल्पित प्रतिक्रिया व संभाव्य विकृति व विकोप इ. सर्व बाबींची संपूर्ण व स्पष्ट कल्पना दिली आहे. मी स्थौल्य हा व्याधिवरील डॉक्टरांनी औषधे घेवून त्यांच्या प्रोजेक्टमध्ये माझ्या मर्जीने सहभागी होत आहे.

रुग्णाची सही

रुग्ण नाम -

डॉक्टर ने मुझे मेरी बीमारी के बारे में पूरी जानकारी दी है। डॉक्टर ने मुझे किए जाने वाले परीक्षणों, दवाओं, उनकी खुराक और संभावित दुष्प्रभावों या अप्रत्याशित प्रतिक्रियाओं और संभावित विकृति और खतरों आदि के बारे में पूरी और स्पष्ट जानकारी दी है। मैं स्वेच्छा से इस बीमारी पर डॉक्टर से दवा लेकर स्टौलिया के प्रोजेक्ट में हिस्सा ले रहा हूं.

रुग्ण हस्ताक्षर