

**UNIVERSITY OF JAMMU
JAMMU & KASHMIR**



COMPLETE PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

SYNOPSIS BY

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**FOR THE DEGREE OF AYURVEDA VACHASPATI
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TITLE OF THE SYNOPSIS

“A RANDOMIZED COMPARATIVE CLINICAL STUDY ON *PATHYADI KWATHA NASYA* AND *PATHYADI KWATHA PANA* IN THE MANAGEMENT OF *ARDHAVBHEDAKA* WITH SPECIAL REFERENCE TO MIGRAINE”

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CERTIFICATE OF SUPERVISION

This is to certify that we will supervise the thesis/research work of **DR. ADITI SHARMA** 1st Year M.D. student, the synopsis of which titled as “**A RANDOMIZED COMPARATIVE CLINICAL STUDY ON PATHYADI KWATHA NASYA AND PATHYADI KWATHA PANA IN THE MANAGEMENT OF ARDHAVBHEDAKA WITH SPECIAL REFERENCE TO MIGRAINE**” 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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ENROLLMENT NO.	

DATED :-

SIGNATURE OF SCHOLAR

INTRODUCTION

Ayurveda is one of the most ancient systems of medicine in India as well as all over the world. *Ayurveda* system of medicine not only deals with diseases but also equivalently deals with preventive aspect of health.

Among all the parts of the body *Shirah* is considered as “*Uttamanga*” and it is the *Ashraya* of the *Prana* and centre of all *Indriyas*^[1]. *Ardhavyabhedaka Roga* is one among the *Shirorogas* mentioned in *Ayurvedic* texts⁽²⁾. *Chakrapani*, the commentator of *Charaka Samhita* had cleared up the term *Ardhavyabhedaka* by saying “*Ardha Mastaka Vedana*”⁽²⁾

Acharya Charaka stated that *Ardhavyabhedaka* is due to vitiated *Vata* or in combination with *Kapha* which seizes the one half of the head and causes acute neuralgic pain in the side of *Manya Pradesh*, *Bhru*, *Shankha*, *Karna*, *Akshi* or forehead of one side. This pain is very agonizing like that of churning rod. If this condition become aggravated it may even impair functions of the eye and ear.⁽³⁾

केवलः सकफो वाऽर्धगृहीत्वा शिरसस्ततः।

मन्याभ्रूशङ्खकर्णाक्षिललाटार्धेऽतिवेदनाम्॥

शस्त्रारणिनिभां कुर्यात्तीव्रां सोऽर्धव्यभेदकः

नयनं वाऽथवा श्रोत्रमतिवृद्धो विनाशयेत्॥ (च.सि.9/75-76)

Ardhavyabhedaka is one of the *Shiroroga* which can be correlated with Migraine having symptoms like paroxysmal one-sided headache. This condition is characterized by the unilateral headache with paroxysmal nature and associated with symptoms like photophobia, nausea, vomiting, and sensory abnormalities.

It is highly prevalent in India (2014), and associated with substantial disability. Prevalence was greater among females (31.6%) vs. among males (18.5%) and in rural areas (28.9%) vs. urban areas (21.7%).⁽⁴⁾ With changing lifestyle patterns, irregular dietary habits, increased mental stress, and exposure to environmental triggers, the prevalence of migraine is increasing globally. Modern pharmacological approaches, including analgesics, triptans, and prophylactic drugs, often provide temporary relief but are associated with significant side effects and dependency risks.

NEED FOR STUDY

In the current era, migraine is one of the most common neurological disorders, affecting approximately 15–20% of the global population, with a higher prevalence in women. It is ranked by the World Health Organization as one of the leading causes of years lived with disability. In today's lifestyle, stress, irregular diet, lack of sleep, and mental strain have made such headaches more common, affecting both personal and professional life. Modern treatment options, though effective for symptom relief, often have limitations such as recurrence, drug dependency, side effects, and high cost, thereby necessitating exploration of safer, sustainable, and holistic approaches.

Ayurveda has a variety of natural medication in the treatment of various types of *Shiro-Roga*. Early and appropriate management of *Ardhavybhedaka* is essential to prevent chronicity, reduce attack frequency, and improve quality of life. Classical formulations, *Panchakarma* procedures (e.g., *Nasya*, *Shirodhara*), and lifestyle modifications based on *Nidana Parivarjana* hold significant potential for preventive as well as curative care.

The Present work an attempt in this direction- “A Randomized Comparative Clinical Study on *Pathyadi Kwatha Nasya* and *Pathyadi Kwatha Pana* in the Management of *Ardhavybhedaka* with Special Reference to Migraine.”

पथ्याऽक्षधात्रीरजनीगुडूचचीभूनिम्बनिम्बैः सगुडः कषायः ।

भ्रूशङ्खकर्णाक्षिशिरोऽर्द्धशूलं निहन्ति नासानिहितः क्षणेन ॥ [भा. प्र. म. ख. 62/56]

Pathyadi Kwatha Nasya⁽⁵⁾ is described in *Bhavprakash Madhyam Khanda* in the management of *Ardhavybhedaka*.

पथ्याक्षधात्री भूनिम्बैर्निशानिम्बामृतायुतैः ॥

कृतः क्वाथः षडङ्गोऽयं सगुडः शीर्षशूलहत् ।

भ्रूशङ्खकर्णशूलानि तथार्धशिरसो रुजम् ॥ [शा.सं. म. खं. .2/143–145]

Pathyadi Kwatha Pana⁽⁶⁾ is described in *Sharangdhara Samhita Madhyam Khanda* in the management of *Ardhavybhedaka*.

PREVIOUS WORK DONE

In Year 2022

Madan Mohan Malviya Government Ayurveda college, Udaipur - Effect of *Pathyadishadang kwath* and *Satahvadya tail Nasya* on Migraine.

In Year 2020

Govt. Akhandanand Ayurved College, Bhadra Ahmedabad, GUJARAT – A Clinico Comparative Evaluation between *Shirobasti* and *Snehan Nasya* along with *Pathyadi kwatha* orally in the management of *Vataj shiraroga*.

In Year 2019

Govt. Akhandanand Ayurveda College, Bhadra Ahmedabad, GUJARAT - Management of *Ardhavybhedaka* (Migraine) with *Tilkalkadi Shirolepa* along with *Pathyadi Kwatha* and *Pathyadi Kwatha* Alone an Open Labelled Randomized Comparative Clinical Trial.

In Year 2018

Patanjali Ayurveda Hospital Patanjali Bhartiya Ayurvedigyan Evam Anusandhan Sansthan Haridwar - A Comparative clinical study on the effect of *Avapeeda nasya* with *Pathyadishadangam kwatha* and *Medha kwatha* in *Ardhavybhedaka* w.s.r to Migraine

In Year 2014

Jammu Institute of Ayurveda and Research, Jammu – Clinical management of *Ardhavybhedaka* w.s.r. to Migraine through *Nasya* and *Pathyadishadang Kwatha*.

In Year 2010

Jammu Institute Of Ayurveda and Research, Jammu - The clinical evaluation of *Dhatryadi Kwatha* And *Shadbindu taila Nasya* in the Management of *Ardhavybhedaka* w.s.r. to Migraine

In Year 2008

IPGT&RA, GAU, JAMNAGAR - A Clinical Study On The Role OF *Brihat Dashamoola Taila Nasya* & *Laghu Sutashekhara Rasa* In The Management Of *Ardhavybhedaka* W.S.R. to Migraine.

AIM

To compare the efficacy of *Pathyadi Kwatha Nasya* and *Pathyadi Kwatha Pana* in the management of *Ardhavybhedaka* with special reference to Migraine.

OBJECTIVES

- 1.To study the etiopathogenesis and symptoms of *Ardhavybhedaka* with special reference to Migraine.
- 2.To evaluate the efficacy of *Pathyadi Kwatha Nasya* in the management of *Ardhavybhedaka* with special reference to Migraine.
3. To re-evaluate the efficacy of *Pathyadi Kwatha Pana* in the management of *Ardhavybhedaka* with special reference to Migraine.

HYPOTHESIS

❖ NULL HYPOTHESIS(H₀)

1. There will be no significant effect of *Pathyadi Kwatha Nasya* in the management of *Ardhavybhedaka* with special reference to Migraine.
2. There will be no significant difference between the efficacy of *Pathyadi Kwatha Nasya* and *Pathyadi Kwatha Pana* in the management of *Ardhavybhedaka* with special reference to Migraine.

❖ ALTERNATE HYPOTHESIS (H_A)

H_{A1}: There will be significant effect of *Pathyadi Kwatha Nasya* in the management of *Ardhavybhedaka* with sepecial reference to Migraine.

H_{A2}: *Pathyadi Kwatha Nasya* will be significantly effective than *Pathyadi Kwatha Pana* in the management of *Ardhavybhedaka* with sepecial reference to Migraine.

H_{A3}: *Pathyadi Kwatha Pana* will be significantly effective than *Pathyadi Kwatha Nasya* in the management of *Ardhavybhedaka* with sepecial reference to Migraine.

REVIEW OF LITERATURE

❖ DISEASE REVIEW

Charaka Samhita

The text identifies a total of nine types. *Acharya Charaka* mentioned five types of *Shiroroga* in Ch.Su.17: *Vataja Shiroroga*, *Pittaja Shiroroga*, *Kaphaja Shiroroga*, *Krimija Shiroroga*, and *Sannipataja Shiroroga*. Their symptoms, prognosis, and treatment approaches are elaborated in *Chikitsa Sthana*.⁽⁷⁾ Additionally, four more varieties—*Shankhakaha*, *Ardhavabhedaka*, *Suryavarta*, and *Anantavata*—are described in *Siddhi Sthana* (Ch. Si. 9).⁽⁸⁾

Sushruta Samhita

In *Sushruta Samhita*, *Uttara Tantra* (Su. Ut. 25/3–4) outlines eleven distinct types of *Shiroroga* along with their therapeutic measures. These include: *Vatika Shiroroga*, *Paittika Shiroroga*, *Kaphaja Shiroroga*, *Raktaja Shiroroga*, *Sannipataja Shiroroga*, *Kshyayaja Shiroroga*, *Krimija Shiroroga*, *Anantavata*, *Shankhaka*, *Ardhavabhedaka*, *Suryavarta*.⁽⁹⁾

Ashtanga Sangraha

In *Ashtanga Samgraha* (A.S.Ut. 27/20–21), *Acharya Vagbhata* describes ten varieties of *Shiroroga* along with their management, referring to them collectively by the term *Shirasatapa*. These are: *Vataja Shiroabhitapa*, *Pittaja Shiroabhitapa*, *Kaphaja Shiroabhitapa*, *Raktaja Shiroabhitapa*, *Sarvaja Shiroabhitapa*, *Krimija Shiroabhitapa*, *Ardhavabhedaka*, *Shirakampa*, *Shankhaka*, *Suryavarta*.⁽¹⁰⁾

Ashtang Hridaya

Ashtanga hridayakara also explains ten types of *shiroroga* and their Lakshanas and their treatment in 23rd chapter of *uttartantra*.⁽¹¹⁾

Madhava Nidana

In *Madhava Nidana* (Chapter 60), *Acharya Madhavakara* presents a classification of eleven types of *Shiroroga*, drawing from both *Sushruta* and *Charaka* traditions.

Sharangdhara Samhita

In the 7th chapter of *puravakhanada* of *sharangdhara samhita*, ten types of *shirorogas* are described as per *Ashtanga Hridya*.

Bhavaprakasha

Acharaya Bhavamishra has mentioned eleven types of *shirorogas* and its management in 62 chapter of *Madhyamakahanda*

DRUG REVIEW

The trial drug under consideration *Pathyadi Kwatha Nasya*⁽⁵⁾ and comparative drug *Pathyadi Kwatha Pana*⁽⁶⁾ contains the same ingredients are *Pathya*,⁽¹²⁾ *Aksha*,⁽¹³⁾ *Dhatri*,⁽¹⁴⁾ *Bhunimba*,⁽¹⁵⁾ *Nisha*,⁽¹⁶⁾ *Nimba*,⁽¹⁷⁾ *Amrita*⁽¹⁸⁾

TABLE NO. 1

Pathyadi Kwatha Nasya⁽⁵⁾ [भा. प्र. म. ख. 62/56]

Pathyadi Kwatha⁽⁶⁾ [शा.सं. म. ख. .2/143–145]

S.No	INGREDIENTS	LATIN NAME	RASA	GUNA	VIRYA	VIPAKA
1.	<i>Pathya</i> ⁽¹²⁾	Terminalia Chebula	<i>Panchrasa</i> (<i>Lavana</i> <i>varjita</i>) <i>Kashaya</i> <i>Pradhana</i>	<i>Laghu, Ruks</i> <i>ha</i>	<i>Ushna</i>	<i>Madhura</i>
2.	<i>Aksha</i> ⁽¹³⁾	Terminalia bellirica	<i>Kashaya</i>	<i>Ruksha, Lag</i> <i>hu</i>	<i>Ushna</i>	<i>Madhura</i>
3.	<i>Dhatri</i> ⁽¹⁴⁾	Embilica officinalis	<i>Panchrasa</i> (<i>Lavana</i> <i>varjita</i>) , <i>Amla</i> <i>Pradhana</i> <i>rasa</i>	<i>Guru,</i> <i>Ruksha</i> <i>Sheeta</i>	<i>Sheeta</i>	<i>Madhura</i>
4.	<i>Bhunimba</i> ⁽¹⁵⁾	Swertia chirayita	<i>Tikta</i>	<i>Laghu, Ruks</i> <i>ha</i>	<i>Ushna</i>	<i>Katu</i>
5.	<i>Nisha</i> ⁽¹⁶⁾	Curcuma longa	<i>Tikta, Katu</i>	<i>Ruksha, Lag</i> <i>hu</i>	<i>Ushna</i>	<i>Katu</i>
6.	<i>Nimba</i> ⁽¹⁷⁾	Azadiracta indica	<i>Tikta,</i> <i>Kashaya</i>	<i>Laghu</i>	<i>Sheeta</i>	<i>Katu</i>
7.	<i>Amrita</i> ⁽¹⁸⁾	Tinospora cordifolia	<i>Tikta,</i> <i>Kashaya</i>	<i>Guru,</i> <i>Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>

ACTIONS OF DRUGS

<u>S.NO</u>	<u>INGREDIENTS</u>	<u>DOSHGHANTA</u>	<u>KARMA</u>	<u>PART USED</u>	<u>PROPORTION</u>
<u>1.</u>	<i>Pathya</i> ⁽¹²⁾	<i>Tridosahara, Vatashamaka</i>	<i>Vednasthapana, Anulomana</i>	Fruit	1 Part
<u>2.</u>	<i>Aksha</i> ⁽¹³⁾	<i>Kaphahara ,Tridoshaghna</i>	<i>Vednasthapana ,Anulomana</i>	Fruit	1 Part
<u>3.</u>	<i>Dhatri</i> ⁽¹⁴⁾	<i>Tridosahara</i>	<i>Anulomana,Mas tishak dorbalyta</i>	Fruit	1 Part
<u>4.</u>	<i>Bhunimba</i> ⁽¹⁵⁾	<i>Tridoshashamaka, Vatapitta shamaka</i>	<i>Anulomana,Nidra janana</i>	<i>Panchanga</i>	1 Part
<u>5.</u>	<i>Nisha</i> ⁽¹⁶⁾	<i>Kaphavata shamaka</i>	<i>Vednasthapana, Anulomana</i>	Rhizome	1 Part
<u>6.</u>	<i>Nimba</i> ⁽¹⁷⁾	<i>KaphaPitta shamaka</i>	<i>Kaphapitta ghana</i>	Bark	1 Part
<u>7</u>	<i>Amrita</i> ⁽¹⁸⁾	<i>Tridosha shamaka</i>	<i>Vednasthapana, Anulomana</i>	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 “*Ardhavybhedaka*” 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** : A randomized, open labelled, comparative, pre and post test clinical study.
- **Level of Study** : O.P.D. & I.P.D. level.
- **Period of Study** : 18 months

FOLLOW UP

- **Follow up:-**
GROUP A (*Pathyadi Kwatha Nasya*)- on 11th day, 21th day, 45th day
GROUP B (*Pathyadi Kwatha Pana*)- on 15th day, 30th day and 45th day
- **Drug free Follow up:-** 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 (Trial Group)	<i>Pathyadi Kwatha Nasya</i>	15 patients
GROUP B (Comparative Group)	<i>Pathyadi Kwatha Pana</i>	15 patients

INCLUSION AND EXCLUSION CRITERIA

❖ INCLUSION CRITERIA

1. Patients of either sex of age between 18 years to 60 years.
2. Patients with clinical features of *Ardhavybhedaka* i.e.Headache,Nausea ,Vomitting,Aura.
3. Patients with Chronicity of disease more than 6 months and less than 3 years.
4. Patients willing to participate and able to provide signed informed consent.

❖ EXCLUSION CRITERIA

1. Patients who are suffering from Hypertension, Diabetes Mellitus and likewise other Chronic diseases.
2. Patients suffering from Cervical Spondylosis,Middle ear infections,Trigeminal Neuralgia and Refractive error.
3. Patients suffering from Fever,Sinusitis.
4. Patients suffering from Secondary Headaches caused by Meningitis,Tumour Encephalitis.
5. Patients with history of Head injury and Brain Infections.

DRUG SELECTION AND PREPARATION

✓ **Collection of drugs :-**

- Ingredients of trial drug *Pathyadi Kwatha Nasya* and *Pathyadi Kwatha Pana* will be procured from the authentic sources, identified and approved by Department of *Dravya Guna*, Jammu Institute of *Ayurveda* and Research, Jammu.

✓ **Preparation :-**

➤ **Trial Drug :- *Pathyadi Kwatha Nasya*⁽⁵⁾**

- The raw ingredients of the *Pathyadi Kwatha Nasya* will be taken in equal parts.
- *Pathya*, *Aksha*, *Dhatri*, *Bhunimba*, *Nisha*, *Nimba*, and *Amrita* will be made into coarse powder in the Department of *Rasa Shastra* and *Bhaishajya Kalpana*, Jammu Institute of *Ayurveda* and Research, Jammu. Using this coarse powder, *Pathyadi Kwatha Nasya* will be prepared in accordance with the classical references as mentioned in *Bhavprakasha*.⁽⁵⁾

➤ **Comparative Drug :- *Pathyadi Kwatha Pana*⁽⁶⁾**

- The raw ingredients of a *Pathyadi Kwatha Pana* will be taken in equal parts.
- *Pathya*, *Aksha*, *Dhatri*, *Bhunimba*, *Nisha*, *Nimba*, *Amrita* will be made into coarse powder in the 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 (Trial Group)

- **Yoga :-** *Pathyadi Kwatha Nasya*⁽⁵⁾
- **Dosage:-** 6 drops in each nostril.⁽¹⁹⁾ (*Virechana Nasya*)⁽²⁰⁾
- **Duration :-** 30 days (3 sittings each consisting of 5 consecutive days; washout period of 5 days)⁽²¹⁾
- **Follow up:-** 11th day, 21th day, 45th day
- **Drug free Follow up :-** on 45th day

➤ Group B (Comparative Group)

- **Yoga :-** *Pathyadi Kwatha Pana*⁽⁶⁾
- **Dosage :-** 48 ml twice a day before meals.⁽²²⁾
- **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⁽²³⁾

1. Severity of headache.
2. Frequency of Headache : Assessed in terms of Frequency in days
3. Duration of Headache : Assessed in terms of Hours/day
4. Nausea
5. Vomiting
6. Vertigo
7. Aura

GRADING OF THE ASSESSMENT CRITERIA ⁽²³⁾

1. Severity of Headache:- ⁽²³⁾

GRADE	SCORE
No headache	0
Mild headache	1
Moderate headache	2
Severe headache	3
Excruciating headache	4

2. Frequency of Headache:- :Assessed in terms of Frequency in days⁽²³⁾

GRADE	SCORE
Nil	0
Once /week	1
Twice/week	2
Thrice/week	3
More than thrice/week	4

3. Duration of Headache:- Assessed in terms of Hours/day⁽²³⁾

GRADE	SCORE
Nil	0
1-3 hrs/day	1
3-6 hrs/day	2
6-12 hrs/day	3
More than 12 hrs/day	4

4.Nausea:-⁽²³⁾

GRADE	SCORE
No Nausea	0
Occasional episodic of brief duration	1
Frequency and prolonged nausea	2

5.Vomiting:-⁽²³⁾

GRADE	SCORE
No Vomiting	0
Present before episode	1
Present before and during episode	2
Present during and after episode	3

6.Vertigo:-⁽²³⁾

GRADE	SCORE
Nil	0
Feeling of giddiness	1
Patient feels as if everything is revolving	2
Revolving signs + black outs	3
Unconscious	4

7.Aura:-⁽²³⁾

GRADE	SCORE
Absent	0
Present	1

LABORATORY INVESTIGATIONS [To rule out other ailments]⁽²⁴⁾

- Hb gm%_s
- Urine Culture and Stool examination

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 the observation which is done on subjective and objective parameters. Result will be analyzed statistically and discussed accordingly.

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