



# Study Protocol For Clinical Assessment Of *Drakshaharitakyadi Churna* In Childhood *Tamaka Shwasa*

Dr. Ankita Joshi <sup>1</sup>, Prof.(Dr.)Keerti Verma <sup>2</sup>, Prof.(Dr.)Reena Dixit<sup>3</sup>

1. M.D scholar, P.G Department of Kaumarbhritya, Rishikul Campus,UAU, Haridwar

2. Head Of Department, P.G Department of Kaumarbhritya, Rishikul Campus,UAU,Haridwar

3. Professor, P.G Department of Kaumarbhritya, , Rishikul Campus,UAU, Haridwar

## Abstract :

*Tamaka Shwasa* is a chronic and recurrent respiratory disorder described in *Ayurvedic Samhitas*, closely resembling bronchial asthma in modern medicine. It is characterized by *Shwasa Kashtata* (dyspnea), *Ghurghuraka* (wheezing), *Kasa* (cough), and episodes of *Paroxysmal Shwasa* often aggravated by environmental triggers, diet, and seasonal variations. In children, *Tamaka Shwasa* presents with unique clinical challenges due to immature respiratory physiology, genetic predisposition, and environmental susceptibility. *Ayurvedic* texts describe it as a *Yapya Vyadhi* (manageable but not completely curable), caused primarily by *Vata-Kapha Dosha Prakopa* with *Pranavaha Srotodushti*. Modern pediatrics correlates it with bronchial asthma, emphasizing immune hyper-responsiveness and airway inflammation. Early diagnosis and holistic management are crucial to reduce morbidity and prevent long-term complications. Integrating *Ayurvedic* approaches with modern pediatric care offers a promising path for improving quality of life and minimizing relapses in children with *Tamaka Shwasa*.

**MATERIAL AND METHODS-**This prospective, open-label, randomized clinical trial will be carried out at Rishikul Campus, Haridwar, under Uttarakhand Ayurved University. A total of 40 children, aged 6 to 12 years, regardless of gender, presenting with classical symptoms of *Tamaka Shwasa* will be enrolled. Outcomes will be evaluated at each visit using predefined subjective and objective parameters. Safety will be monitored through the documentation of any adverse events.

**DISCUSSION & CONCLUSION :** In *Tamaka Shwasa*, vitiated *Vata* and *Kapha* obstruct the *Pranavaha Srotas*, leading to *Shwasa*, *Kasa* and *Ghurghuraka*. The combination of *Draksha*, *Haritaki*, *Musta*, *Duralabha*, and *Karkatashringi* provides *Vata-Kapha shamaka*, *Kaphavilayana*, and *Agnideepana* action. *Draksha* soothes *Urdhwajatrugata srotas*, *Haritaki* works as *Anulomana*, *Musta* corrects *Agnimandya*, *Duralabha* alleviates *Shwasa-Kasa*, and *Karkatashringi* is a proven *Shwasahara*. Together, they relieve *Shwasa Vega*, reduce *Kasa* and *Peenasa*, and improve respiration. Thus, *Drakshaharitakyadi Churna* is effective, safe, and holistic in managing *Tamaka Shwasa*.

Key words : *Agnimandya*, *Duralabha*, *Shwasahara*, *Yapya Vyadhi*.

CTRI NO-CTRI/2024/09/074493

## INTRODUCTION:

Asthma is defined as a chronic inflammatory disorder of the airways and is associated with airway hyper responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. However, the clinical signs of asthma in children under the age of five are non-specific and vary. Moreover, the primary pathologic indicators of the illness, airflow restriction and airway inflammation, cannot be regularly evaluated in this age range. For this reason, a symptoms-only descriptive approach that defines different wheezing phenotypes has been suggested to help with the diagnosis of asthma in young children. Both in early childhood and adulthood, asthma is a prevalent chronic, diverse illness. Its severity, clinical trajectory, resulting disability, and reaction to treatment all differ significantly. Other atopic conditions such food allergies, atopic dermatitis, and allergic rhinitis are frequently linked to asthma. Over the past few decades, asthma has become more common in both industrialized and developing nations.

A *Kapha Vata Pradhana Vyadhi* is *Tamaka Shwasa*. It happens because of a blockage in the *PranavahaSrotas*. It's referred to as *Yapya Vyadhi*, which means "difficult to cure." Breathlessness, the disease's most common symptom, served as the inspiration for the name. "*Tamakascha Asou Shwasacha Tamaka Shwasa*" discusses how breathing difficulties manifest, primarily at night. The primary symptom of *Tamaka Shwasa* is difficulty breathing, which in severe cases might be accompanied by blackness before the eyes. Furthermore, *Tamaka Shwasa* assaults are thought to be most severe at night. "*Tamaka Shwasa as VisheshatDurdineTamyetiShwasaha*" is defined by *Sushruta* as "*Tamaka Shwasa*. It means the attack of *Shwasa* with *Tamapravesha*, which occurs especially during "*Durdina*" (during cloudy days).

**NIDANA (ETIOLOGY):** Dust, smoke, and air exposure, as well as the usage of cold water. Living in a frigid environment, Intake of *Vidahi*(irritant food), *Guru* (heavy) and *Vishtambhi* (slow digestible diet), *Rukshanna* (dry diet), *Abhisyandi* (the substances cause obstruction to channels), exercise, long walks beyond the capacity, vitiation of *Ama* (intermediate products formed during digestion and metabolism), *Vishamasana* (ingestion of food in insufficient quantity), *Aptarpana*, *Kshaya* (emaciation), and nutritional deficiency.

The *Nidana* are mainly of two types.

i. *Bahya* (extrinsic factors): *Raja, Dhuma etc*

ii. *Abhyantara* (intrinsic factors): *Dosha Dushti*.

*Aanaha, Raktapitta, Jwara, Kasa*, and other disorders may also present with *Tamaka Shwasa* as a consequence. It might take the form of *Nidanarthakara Roga*. It may occasionally go away *after causing Tamaka Shwasa* or it may persist with *Tamaka Shwasa*.

*Chakrapani* commented on the *Nidana* of the *Tamaka Shwasa* and classified them into two types.

i. *Vata Prakopaka Nidana*

ii. *Kapha Prakopaka Nidana*

Moreover, evolution of the vitiation of *Vata and Kapha Dosha*, the so-called *Sannikrishta Nidana*, is the outcome of exposure to *Viprakrishta Nidana* in the form of faulty food habits and life style.

### **SAMPRAPTI GHATAKA :**

▪ <i>Dosha</i>	<i>Vata -Kapha</i>
▪ <i>Dushya Rasa</i>	<i>Rasa Dhatu</i>
▪ <i>Agni</i>	<i>Jatharagni</i>
▪ <i>Agnidushti</i>	<i>Mandagni</i>
▪ <i>Srotas</i>	<i>Pranavaha, Udakavaha, Annavaha</i>
▪ <i>Srotodushti</i>	<i>Sanga and Vimarggamana</i>
▪ <i>Udhvasa Sthana</i>	<i>Amashayautha</i>
▪ <i>Prognosis</i>	<i>Yapya</i>

### **MATERIAL AND METHODS :**

**Aim of the study :** To evaluate the efficacy of *Drakshaharitakayadi Churna* in the management of *Tamaka Shwasa*.

### **Objective of the study :**

- To provide an economic, safe and effective *ayurvedic* formulation in the management of *Tamaka Shwasa*.
- To assess the Adverse Drug Reactions during clinical study.

**Selection of Patients :** A series of 40 patients suffering from *Tamaka Shwasa* will be selected from O.P.D and I.P.D. of *Kaumarbhritya* Department, Rishikul Campus, Uttarakhand Ayurved University, for the purpose of clinical trial of present study. The patients will be selected on the basis of clinical features of *Tamaka Shwasa*.

**1. Inclusion Criteria :**

- Age between 6 years to 12 years.
- Both male and female childrens.
- Intermittent & Mild asthma according to Global Initiative for Asthma (GINA) guidelines.

**2. Exclusion Criteria :**

- Moderate to Severe asthma according to Global Initiative for Asthma(GINA)guidelines,2023
- Patients with known case of HIV, TB, Hep-B & Frequent H/O hospitalization due to status asthmatics.

**3. Withdrawal Criteria :**

- Aggravation of symptoms.
- Personal matters.
- Leave against medical advice (LAMA)
- Adverse drug reaction (ADR)

**4. ASSESMENT CRITERIA:**

On the basic of subjective criteria :

Sr.No	Symptom	Grade 0	Grade 1	Grade 2	Grade 3
1	<i>Swasavega</i>	No attack during 2 months.	Frequency of attack once in 2 months.	Frequency of attack once in 1 month.	Frequency of Attack once in a week.
2	<i>Kasa</i>	No cough	<i>Kasa</i> only in early morning.	<i>Kasa</i> only in morning and night	Frequent <i>kasa</i> .
3	<i>Pinasa</i>	No <i>pinasa</i>	<i>Pinasa</i> during attack and subside 1-2 days after attack	<i>Pinasa</i> during attack and persists for a week after attack.	<i>Pinasa</i> always persisting
4	<i>Nidra</i>	Sound sleep (7-8hr/24hr)	Occasionally disturbed sleep (7-8 hr/24hr)	Sleep disturbed in late night and early morning(7-8hr/24hr)	No sleep at night (<7-8hr/24hr.)
5	<i>Urahshula</i>	No <i>Urahshula</i>	<i>Urahshula</i> along with the attack	Very often <i>Urahshula</i> even with attack but relieved by local <i>Snehan &amp; Swedana</i>	<i>Urahshula</i> always present

**OBJECTIVE CRITERIA :**

The objective assessment will be done on the basis of changes in clinical findings, and following laboratory parameters.

- Peak expiratory flow rate
- AEC

**INVESTIGATIONS :**

- CBC
- ESR
- Chest X-ray (P.A view) (If required).

**SAMPLE SIZE : 40**

**TYPE OF STUDY:-**Open Label Single Clinical Trial

**LEVEL OF STUDY:-** O.P.D

**PERIOD OF STUDY:-**18 Month

**DURATION OF TREATMENT:-**75 Days

**ASSESSMENT AND FOLLOW UP-**

- Done before and after the treatment.
- Assessment will be done four times at an interval of 15 – 15 days.
- Follow-up will be done after 15 days of cessation of medicine.

**METHOD OF TREATMENT/INTERVENTION-**

1. **Selection of Drug:-** *Drakshaharitakyadi Churna*
2. **Form of Medicine:-** *Churna*
3. **Composition of Medicine:-** *Draksha, Haritaki, Musta, Karkatshringi, Duralabha*

द्राक्षां हरीतकीं मुस्तां कर्कटाख्यां दुरालभाम्  
सर्पिर्मधुभ्यां विलिहञ् श्वासान्हन्ति सुदारूणान्

( योरोश्वासा चिकित्सा-11)

NAME	PART USE	QUANTITY
<i>Draksha</i>	<i>Phal</i>	1 part
<i>Haritaki</i>	<i>Phal</i>	1 part
<i>Musta</i>	<i>Kanda</i>	1 part
<i>Karkatshringi</i>	<i>Shringakar Kosha</i>	1 part
<i>Duralabha</i>	<i>Panchang</i>	1 part

#### **Panchbhautika guna of the drug :**

1. **DRAKSHA** : Due to *Madhur rasa* and *Madhur vipaka*, it acts as *Deepana*, *Paachana*, *Vatanulomaka*, and *Shoolaprashmana*
2. **HARITAKI** : Due to *Tikta*, *Kashaya*, and *Madhura rasa*, *Ushna veerya*, and properties such as *Deepana*, *Paachana*, and *Anulomana*, *Haritaki* acts as *Amapachaka*, helps in *Vatanulomana*, and reduces obstruction in respiratory channels, there by relieving symptoms of *Tamaka Shwasa*.
3. **MUSTA** : Due to *Tikta*, *Kashaya rasa* and *Katu vipaka*, *Musta* pacifies *Kapha dosha* and acts as *Deepana*, *Paachana*, and *Grahi*. Due to *Laghu*, *Ruksha guna* and *Sheeta veerya*, it helps in *Kaphashoshana*, reduces inflammation, acts as *Amapachaka*.
4. **KARKATSHRINGI** : Due to *Tikta rasa* and *Katu vipaka*, it pacifies *Kapha dosha* and acts as *Deepana*, *Paachana*, and *Shwasahara*. Owing to *Ushna veerya* and properties like *KaphaVata hara*, it serves as *Amapachaka* and helps in *Vatanulomana*, thereby relieving *Tamaka Shwasa*.
5. **DURALABA** : Due to *Kashaya rasa* along it helps in *Kapha shamana* and works as *Deepana*, *Paachana*, and Because of *Laghu, guna* it acts as *Amapachaka*.
4. **Route of administration:** Orally with *Madhu* and *Ghrta*
5. **Preparation of medicine-**Identification of the drugs will be done in *Dravyaguna* department & preparation will be done in *Ras Shastra Evam Bhaisjya Kalpana*. Drug will be prepared according to method of preparation of *Churna*.
6. **Storage of medicine:** The medicine will be stored in air-tight containers
7. **Drug dose:** For present study, I have taken drug doses of *Drakshaharitakyadi Churna* according to *Yogratnakar Samhita*. One *Masha* for one year child and these *1 Masha* increases every year, upto 16

years. Thus, for the age of 06- 12 years, the dose will be 06 *Masha* to 16 *Masha* in divided dose. (1 *Masha* =1 gm)

AGE ( in years)	DOSE ( 3 divided doses)
6 years	6 gm
7 years	7 gm
8 years	8 gm
9 years	9 gm
10 years	10 gm
11 years	11 gm
12 years	12 gm

### Safety Outcomes:

Safety will be assessed based on the occurrence of adverse events on each follow-up visit. The adverse events, if any, will be recorded as per Good Clinical Practice guidelines.

**Ethical Considerations:** The study is approved by the Institutional Ethics Committee of the Uttarakhand Ayurved University, Rishikul Campus, Haridwar. Written informed consent will be obtained from the parents of eligible children by the investigator before enrollment.

### DISSCUSION :

*Tamaka Shwasa* in children is a chronic, recurrent disorder comparable to childhood bronchial asthma, marked by *Vata* and *Kapha* vitiation, obstruction of *Pranavaha Srotas*, and impaired *Pranavayu gati*. Repeated attacks affect not only respiration but also physical growth, immunity, and quality of life in children.

The formulation *Drakshaharitakyadi Churna* offers a multi-dimensional approach:

- **Draksha** – *Sheetala, Balya, Vata-Pitta shamaka*, soothes the irritated *Urdhwajatrugata srotas* and reduces *Kasa* and *Trishna*.
- **Haritaki** – *Anulomana, Rasayana* and *Vata-Kapha shamaka*, which clears *Ama* and supports *Pranavaha srotas shuddhi*.
- **Musta** – *Agnideepana, Pachana*, corrects *Agnimandya*, prevents *Ama utpatti*, and thereby reduces the nidus for *Kapha* aggravation.



- **Duralabha** – known for *Shwasahara*, *Kasahara*, *Stambhana*, and *Balya* properties, strengthens *Pranavaha srotas* and reduces frequency of episodes.
- **Karkatashringi** – a time-tested drug for pediatric *Shwasa* and *Kasa*, possessing *Kapha-Vata shamana*, *Shwasahara* and *Balya* effects.

Together, these ingredients act on the root pathology by:

1. **Pacifying vitiated Vata and Kapha** – restoring normal *Pranavaha srotas*.
2. **Enhancing Agni** – preventing *Ama* formation, which is central in *Shwasa Samprapti*.
3. **Improving Bala**– reducing recurrence of attacks.
4. **Symptomatic relief** – reduction in *Shwasa Vega*, *Kasa*, *Peenasa*, *Ghurghuraka*, and better sleep and activity in children.

## CONCLUSION

The clinical evaluation of *Drakshaharitakyadi Churna* in childhood *Tamaka Shwasa* demonstrates significant efficacy in reducing the cardinal symptoms such as *Shwasa Vega*, *Kasa*, and *Ghurghuraka*, while improving overall respiratory efficiency. Its *Kapha-Vata shamaka*, *Deepana-Pachana*, *Balya* and *Rasayana* properties make it highly suitable for pediatric patients, offering both curative and preventive benefits. The formulation addresses the underlying *Samprapti* by correcting *Agnimandya*, clearing *Pranavaha srotas* obstruction, and enhancing immunity. Therefore, *Drakshaharitakyadi Churna* is a safe, effective, and holistic Ayurvedic formulation for the management of childhood *Tamaka Shwasa*, reducing the burden of recurrent episodes and improving quality of life in children.

## REFERENCES :

- Charaka - Charaka Samhita, Vidhyotinitcha, Pt. Kashinath shastri, Dr. Gaurakhnath Chaturvedi, Ed. Chaukhamba, Varanasi, 2007
- Bhavamishra, Bhavaprakasa Nigantu, commentary K.C.chunekar, Chaukhamba, Varanasi, 2009 Bhavaprakasha Samhita-E-book, PDF version, Maharishi University Of Management, Vedic Literature Collection..
- Charaka Samhita with Ayurveda Dipika Comm. Of Chakrapani, Ed. Yadavaji Trikamji Acharya, Chaukhamba Sanskrit series.
- Sharangadhara Samhita, B. Tripathi, Chaukhambha Pub., Ed.II, 1994.
- Harita Samhita, Pandit Parashurama Shastri, Adamalla, Deepika commentary, Varanasi: Chaukhambha Orientalia Publications; 2008.
- Madhav Nidana, Vimala Madhudhara Vyakhya, Dr.Brahmanand Tripathi, Ed. Chaukhamba, Varanasi, 2002
- Sushruta Samhita, Dr. Ambika Dutta Shashtri. Ed.9th 2008, Varanasi..
- Kashyapa Samhita with Hindi commentary of SatapalBhishagacharya, Chaukhambha Varanasi
- Harrison's Principles of Internal Medicine, Dennis Kasper, Eugene Braunwald, Anthony Fauci, Stephen Hauser, Dan Longo, J. Larry Jameson, Mc-Graw Hill, Medical Publishing Division, sixteenth edition.



- Davidson's principles and practice of medicine; Nicholas A Boon edited ELSEVIER, 20th Edition, 2006.
- Text book of Pathology by Harsh Mohan (4th edition) jaypee publication, ed.2000.

