STUDY PROTOCOL

Evaluation of comparative efficacy of cow milk treated Sida Cordifolia oil nasal administration (Ksheerbala Taila Nasya) versus Convolvulus pluricaulis oil nasal administration (Shankapushpi Taila Nasya) in the management of primary insomnia (Anidra)- a trial protocol

[version 1; peer review: 2 approved]

Dr.Annya Gautam, Dr.Vinod Ade

Panchakarma, Mahatma Gandhi Ayurved College Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, 442001, India

v1 **First published:** 18 Oct 2023, **12**:1370
https://doi.org/10.12688/f1000research.139513.1
Latest published: 18 Oct 2023, **12**:1370
https://doi.org/10.12688/f1000research.139513.1

Abstract

Background: Ayurveda, formerly known as the "Science of Life," is a distinct science and philosophy that aims to achieve comprehensive wellbeing by balancing the psychological, emotional, spiritual, and physical facets of life. The three basic principles listed by Ayurveda to maintain good health are Food (Ahara), sleep (Nindra), and Celibacy (Bramhacharya). According to Ayurveda, it is a strong rigid support of life. Many people today depend on sleeping pills and have developed a dependence on them. Potentially harmful side effects of sleeping drugs include drowsiness during the day, constipation, dizziness, and problems maintaining equilibrium. It is said that a vitiated Vata Dosha sets off the effects of insomnia, hence balancing Vata Dosha can provide relief in the event of Insomnia. Convolvulus Pluricaulis (Shankhpushpi) herb is a memory enhancer that can also be used as a brain tonic to stimulate brain and brain function. According to Ayurveda, the entrance to the brain is through the nose. Nasal administration refers to the practice of administering medication nasally. It is the most important therapy to treat upper clavicular disease.

Objective: To study the evaluation of comparative efficacy of cow milk treated sida cordifolia oil nasal administration (Ksheerbala Taila Nasya) versus Convolvulus Pluricaulis Oil Nasal Administration (Shankapushpi Taila Nasya) in the Management of Primary Insomnia (Anidra)-RCT

Protocol: In this study, a total of 128 patients will be divided into two groups. In group, A (64 patient) cow milk treated with Sida Cordifoila

Open Peer Review

Approval Status ✓ ✓

	1	2
version 1 18 Oct 2023	✓ view	✓ view

1. **Manjusha Sunil More**, Shree Saptashrungi Ayurved Mahavidyalaya and Hospital, Nasik, India

2. **Anup Jain**, Charak Brahm Prakash Ayurved Charak Sansthan, Najafgarh, India

Any reports and responses or comments on the article can be found at the end of the article.

Oil Nasal Administration will be administered eight drops in each nostril for 15 days. The same will be used for the other 64 patients i.e., group B with Convolvulus Pluricaulis Oil Nasal Administration. Expected result: The result will be assessed on the objective parameter and data will be compared after the treatment.

Keywords
Insomnia , Nasal Administration , convolvulus pluricaulis , sida cordifolia, oil

This article is included in the Datta Meghe Institute of Higher Education and Research collection.

Corresponding author: Dr.Annya Gautam (ananyagautam68@gmail.com)

Author roles: Gautam DA: Writing – Original Draft Preparation, Writing – Review & Editing; **Ade DV**: Conceptualization, Methodology, Supervision, Validation

Competing interests: No competing interests were disclosed.

Grant information: The author(s) declared that no grants were involved in supporting this work.

How to cite this article: Gautam DA and Ade DV. **Evaluation of comparative efficacy of cow milk treated Sida Cordifolia oil nasal administration (Ksheerbala Taila Nasya) versus Convolvulus pluricaulis oil nasal administration (Shankapushpi Taila Nasya) in the management of primary insomnia (Anidra)- a trial protocol [version 1; peer review: 2 approved]** F1000Research 2023, **12**:1370 https://doi.org/10.12688/f1000research.139513.1

First published: 18 Oct 2023, **12**:1370 https://doi.org/10.12688/f1000research.139513.1

Introduction

One of the most well-known traditional medicinal practices from antiquity that has survived and developed over time is ayurveda. This system will endure for many more millennia because of the extensive knowledge of natural remedies, the linkages between environmental factors and human body composition and performance, and the cosmos's interconnected elements that have an impact on living things.[1]

Panchkarma (detoxification therapy) is an Ayurvedic detoxifying retreat technique. *Panchkarma* is a detoxification and relaxing approach that has been used for centuries to help people cope with seasonal and societal changes. Benefits of this therapy include improvements in one's perception of social support, quality of life, and healthy behavior.[2]

For daily activities, focus, alertness, mental and physical performance, etc., sleep is crucial. Sleep disruptions can lead to serious health issues and other difficulties.

An individual who struggles to fall or stay asleep is said to have insomnia. Short-term and longer insomnia are both possible; short-term insomnia can last anywhere from one night to a few weeks, while long-term insomnia develops when sleep problems endure for longer than three months. Primary and secondary insomnia are the two categories of the condition. In contrast to secondary insomnia, which occurs when a patient's sleep problems are brought on by an underlying health problem such as asthma, cancer, heartburn, pain, medications, or other substances such as alcohol whereas primary insomnia is characterized by the absence of any other health concerns in the patient.[3]

The three pillars of life in Ayurveda are food (*Ahara*), sleep (*Nindra*), celibacy (*Bramhacharya*), according to a Hindu religious teacher, insomnia is mentioned in the *Charaka Samhita*, *Susruta Samhita*, and *Astang Hridaya*, among other ayurvedic classic texts.[4] Insomnia is defined in eight undesirable conditions (*Asthonindtiya Adhyaah)* by spiritual guide Charak, and insomnia is mentioned in *Maharoga Adhyaya* as one of the 80 types of *Vata* disease.[5] It is described in the *Susruta Samhita* in the *Sharir Sthana* under *Garbhavyakaran Sharir.*

The causes of insomnia, according to Acharya *Sushruta*, are *Santapa* of *vaata, pitta*, and *mana*, as well as physical harm. Insomnia is caused by a variety of factors, the most prevalent of which are listed above.[6] In *Astang Hridiya* spritual guide *Vaghbhat* has quoted the symptoms of insomnia as following throbbing pain, heaviness in head, yawning, stiffness all over body, exhaustion, giddiness, indigestion, drowsiness it may further causes *Vata* disease.[7] It is said that a vitiated *Vata Dosha* sets off the effects of insomnia, hence balancing *Vata Dosha* can provide relief in the event of insomnia.

Insomnia is said to affect 9% of the general population, with 30% of people experiencing it occasionally. 18.6% of the cohort research participants said they had sleeplessness. A north Indian urban population was found to have a greater prevalence of sleep disorders (28%) that affect the onset and maintenance of sleep.[8]

Convolvulus pluricaulis herb is a memory enhancer that can also be used as a brain tonic to stimulate brain and brain function. It improves focus and learning capacities while also assisting in the treatment of insomnia, stress, depression, and mental stress.

Convolvulus pluricaulis characterizes bitter taste. It shows oily, sticky, and slimy property, cold potency, and sweet metabolic property help in preventing a variety of health problem that disrupt sleep.

The intellectual effect boosts mental power and hence resists depression and anxiety etiology, resulting in restful sleep. *Shankhpushpi* is known to lower cortisol (the stress hormone), reducing stress and improving the quality and quality of natural sleep. Gastric problems can disrupt sleep, but this magical herbal remedy aids digestion and prevents reflux and gas accumulation, allowing you to sleep better. Chemical components found in Shankhpushpi, such as Shankhapushpine, convoline, convolidine, confoline, myristic acids, scopoletin, -sitosterol, tetratriacontane acids, flavonoid-kaempferol, and phytosterols, help to boost general health and ward off sickness- resulting in insomnia.[9]

According to Ayurveda, the entrance to the brain is through the nose. Nasal administration refers to the practice of administering medication nasally. It is the most important therapy as it is used for the treatment of upper clavicular disease so in some places it has been given first place in the sequence of detoxification for e.g., in the chapter of *Apamarga Tanduliyam* of *Charaka Samhita Sutrasthana.*

The medication used in nasal administration enters the brain via a pathway known as the Vital point (*Shringataka Marma)*, where it destroys the connection between toxins and brain tissues before transporting those molecules to the

nose, where secretions force them out. People with brain illnesses are frequently given large amounts of unwanted medications by mouth. This may become troublesome for a patient's health if they live a long time or if they have a chronic ailment. Because of the brain's blood barrier restriction to oral use, tablets delivered orally are an incredibly poor approach to deliver medications to the brain when it comes to brain illnesses. Sneha can cross the blood-brain barrier because to its lipophilic activity, which releases the active principles of the constituents where they are needed. The likelihood that a medicine will cross the blood-brain barrier increases with its lipophilicity.[10]

Need of the study

In present era, Digital media and smart phones have raised productivity demands while blurring the boundaries between work and personal life. All these factors, including reduced free time, a faster pace of life, and stress, contribute to sleep deprivation, which has major medical and emotional consequences, health, job performance, and overall quality of life are all factors to consider.

Modern medical research has therapies such as hypnotics, sedatives, anxiolytics, and psychotropics, but there is still no definitive cure for insomnia, and these medications have their own set of limitations due to their side effects.[11] Due to their addiction and side effects, current anxiolytic medications have a limited application.[12]

As a result, these drugs cannot be used for an extended period. As a result, it is crucial to seek out drugs from natural systems of medicine such as Ayurveda that are both safe and successful in treating insomnia patients. Hence this study is conducted with the aim evaluation of comparative efficacy of cow milk treated *Sida Cordifolia* oil nasal administration (*Ksheerbala Taila Nasya)* versus *Convolvulus Pluricaulis* oil nasal administration (*Shankapushpi Taila Nasya*) in the management of primary insomnia (*Anidra*).

Aim

Evaluation of Comparative Efficacy of cow milk treated *sida cordifolia* oil nasal administration (*Ksheerbala Taila Nasya)* versus *convolvulus pluricaulis* oil nasal administration (*Shankapushpi Taila Nasya*) in the Management of Primary Insomnia (*Anidra*).

Objectives

1. To assess the efficacy of *Shankahpushpi Taila Nasya* in the PSQI (PITTSBURG SLEEP QUALITY INDEX), Insomnia Severity Index, WHO Quality of life scale.

2. To assess the efficacy of *Ksheerabala Taila Nasya* in the PSQI (PITTSBURG SLEEP QUALITY INDEX), Insomnia Severity Index, WHO Quality of life scale.

3. To Compare the efficacy of of *Shankhpuspi Taila Nasya* with *Ksheerbala Taila Nasya* in all three scale in the management of Primary Insomnia (*Anidra*).

Trial design- Randomization standard control double blind superiority clinical trial.

The allocated intervention will blind participants.

Protocol

Study setting

The patient of Insomnia will be recruited from the panchakarma OPD and IPD of Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod(H), and from peripheral camps.

A total of 60 patients will be recruited for the study. They will be randomly divided into two groups. Group A will be given nasal administration with *Ksheerbala* oil, Group B will be given nasal administration with *Shankhapushpi. All* the baseline parameters will be recorded at the start of the study. The patients will undergo treatment for 15 days for both groups. After treatment, all the parameters will be recorded at the 16^{th} and 30^{th} day.

Guideline: Used the SPIRIT guideline for the study.

Case definition: Patient of insomnia (having age group between 20-60 year of irrespective gender) diagnosed based on Insomnia Severity Index.

Sampling procedure: Randomization computer generated table.

Type of Study: Interventional Study

Study design: Refer to Figure 1.

Study design: Randomization standard control double blind superiority clinical trial.

Roles and Responsibilities of committees: The study will start after clearance from IEC of Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod(H), Wardha. And after CTRI registration Ref.No. MGACHRC/IEC/June-2023/707

The committee will decide on the endpoint and oversee the trial as it progresses.

The researcher will assess any adverse events and will report to the ethics committee.

Inclusion criteria

1. Patients who are willing to give written inform consent.
2. Patients' gender age is between 20-60 years.
3. Patients who are fit for Nasal administration procedure.
4. Patient with controlled hypertension
   - (Systolic not more than 140 mmHg and diastolic not more than 90 mmHg).
5. ICD10 criteria for primary insomnia – F51.01
   - Problems falling asleep or staying awake.
   - Sleep varies, i.e., one night of good sleep comes after several nights.
   - Daytime sleepiness.
   - Problems in performing daily activities.

Participants timeline-

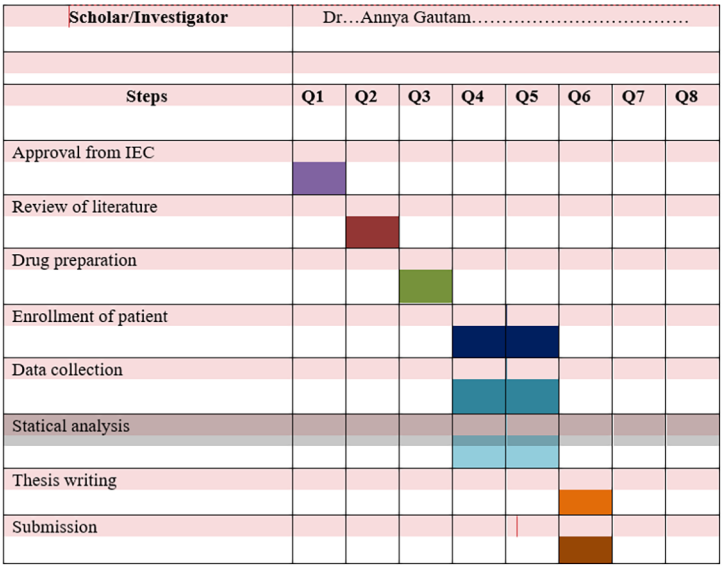

Figure 1. GANTT Chart for study (Timeline).

Exclusion criteria

1. Patients < 20 years and > 60 years.
2. Pregnant women and lactating mothers.
3. Patient with co-morbidities Ex. uncontrolled Hypertension, DM-2, Thyroids, Cardiac disorders.
4. Patient not fit for nasal administrating procedure, Rhinitis, Thirst, Indigestion, Menstruation etc.
5. Patients with drug dependency like Antihistamines, Narcotics.

Occupational disease.

Detail of drug preparation

S. No.	*Dravya*	Latin Name	*Rasa*	*Guna*	*Virya*	*Vipaka*	*Doshgh nta*
1.	*Shankhapushpi*	Convolvulus Pluri culis	Bitter	Sticky, Slimy	Cold	Sweet	*Balance pitta and kapha*
2.	*Tila taila*	Sesamum indicum	Sweet Bitter	Subtle, stable	Hot	Sweet	*Vata shamak*

Detail of drug preparation[13]

The coarse powder of the *kalka Dravya* will be taken in *khalva yantra* and triturated with little quantity of water till we obtain *kalka (Paste).*

Now, *tila taila* will be consumed in a clean stainless-steel vessel with wide opening that is set over low flame.

Then, *shankhapushpi kwatha (decoction)* and water followed by kalka will be added and processed with frequent stirring.

Then as soon as all the *Sneha siddhi lakshanas will be* attained, the hot *taila* will be filtered into a clean stainless-steel vessel.

Then, after the tail cool down by its own, it is packed and preserved in appropriate airtight containers for further therapeutic use.

Procedure of nasal administration[14]

1. Pre-procedure
2. Procedure
3. Post-procedure

Pre-procedure

All of the necessary tools and supplies should be acquired and organized prior to the procedure. The drugs required for Procedure i.e., Paste, Powder, Milk, Decoction should be available in a separate room free of dust, with direct air flow, sufficient lighting, Nasal administration table, and material required (the drugs required for procedure *i.e.,* Paste, Powder, Milk, Decoction, nasal dropper, cotton swab, oil, medicinal smoke machine. A special smoke machine is required for *Pradhamana Nasya.* An attendant, as well as dressing tools, a spittoon, napkins, bowls, and towels, should be available.

The patient should be appropriately prepared by ensuring that they thoroughly comprehend the procedure and that they are willing (permission) to carry it out. Before lying down on the nasal administration table, the patient is recommended to pass his or her natural cravings. Soft and gentle massage should be done on scalp, forehead, face, neck for approximately 10-15 minutes using medicated oil. For the liquefaction of the Dosha, mild sudation (*mridu swedan*) should be performed, Mild sudation must be administered with caution, as sudation *should* not be performed on the head region, according to *Ayurveda's* classical text.

Procedure

The patient should be advised to lie down on the nasal administration table in a supine posture with his or her head hanging downward and not overly stretched or flexed. The reason behind this is because if the head is not appropriately lowered, the injected medicine may miss its target, and if it is lowered too much, the drugs may reach the brain and become lodged there. Cotton or cloth should be used to cover the patient's eyes. The physician should next use the left thumb to lift the tip of the nose, and the right hand to pour the medicine into the nostrils. The drug should be taken in the correct amount, neither too much or too little. Depending on the patient's tolerance, it should be lukewarm. The patient should be encouraged to remain cool and composed throughout the process, and to refrain from speaking, laughing, sneezing, or shaking his head. Then keep the patient lying down and observe the symptoms arising in him.

Observation

Proper Sudation (*Samyak Yoga*)	**Improper sudation (*Asveda Lakshana*)**	**Excessive Sudation (*Atisvedana Lakshana)***
Lightness in head region *(Shiro laghav)*	No relief of coldness (*Sita Aprasama*)	Fainting (*Murccha*)
Good Sleep *(Sukhaswapana)*	No sweating (*Sveda Aapravrutti*)	Burning sensation (*Daha*)
Remission of disease (*vyadhihani*)	No relief of pain (*Sula Aprasama*)	Weakness (*Daurbalya*)
Improve sense organ (*Indriyashuddhi)*	Itching (*Kandu*)	Appearance of blister (*Sphotha Utpati*)
Cleans the channels (*Shrotoshuddhi)*	Heaviness (*Gourava*)	Exhaustion (*Klama*)
Relief stiffness (*Stambha Nigraha*)	----------	Pain in joints (*Sandhipida*)

Nasal administration complications and its management

There are two varieties of complication, according to *spiritual guide Sushruta*: *Dosha Vriddhi Janya*, Secondly, *Dosha Kshaya Janya Vyapad. Shodhana* and *Shaman Chikitsha* should be stated in the case of *Dosha Vriddhi Janya Vyapad*, while *Brihmana Chikitsa* is recommended in the case of *Dosha Kshaya Janya Vyapa.*

Paschatkarma

The patient should be asked to lie in a supine position for roughly 1 minute after receiving the nasal medication, and the feet, shoulders, palms, and ears should be massaged during this time. If there is too much of a certain medicine, it should be spit out rather than consumed. The remnant *Kapha* Dosha that may be lodged in the Kantha and *Sringataka Marma* is then expelled with medicated *Gandusha* and medicated smoke. After that, the patient should be encouraged to stay in a room with no breeze, eat a light meal, and drink plenty of water.

Assessment criteria:

Objective criteria:

(A) PSQI (PITTSBURG SLEEP QUALITY INDEX)[15] [Table- 1]

(B) INSOMNIA SEVERITY INDEX[16] [Table – 2]

(C) QUALITY OF LIFE[17] [Table – 3]

Investigations: NIL

Sample size-

Sample size by Cohen's effect size by comparing two means.

Primary Variable: - Insomnia Assessment by PSQI Scale and Insomnia Severity Index.

(Estimated)

Considering large effect size difference = 0.8 (Large effect size)

Sample size

at 5 % level of significance = 1.96

at 80 % Power = 0.84

Ratio allocation (Group2/Group1) = 1

Sample size = 26 per group.

Considering 15 % drop out total = 4

Total 30 samples required per group. Sample size by Cohen's effect size by comparing two means.

Primary Variable: - Insomnia Assessment by PSQI Scale and Insomnia Severity Index.

(Estimated)

Considering large effect size difference = 0.5 (Medium effect size)

Sample size

at 5 % level of significance = 1.96

at 80 % Power = 0.84

Ratio allocation (Group2/Group1) = 1

Sample size = 64 per group.

Considering 10 % drop out total = 6

Total 70 samples required per group.

Recruitment

The patient of insomnia will be selected from the panchakarma OPD and IPD of Mahatma Gandhi Ayurved College, Hospital & Research centre, Salod(H), and from peripheral camps. A total of 60 patients will be recruited for the study.

Allocation sequence generation- Computer-Generated Random Numbers.

Allocation implementation- The researcher or the first author will generate an allocation sequence, enroll participants, and assign participants to intervention.

Blinding- Double blind superiority clinical trial.

Data collection plan

Group	Sample Size	Intervention	Dose and Frequency[18]	Duration	Follow-up
A	30	Cow milk treated with Sida Cordifolia oil nasal administration (*Ksheerbala Taila Nasya)*	8 drops each Nostrils	15 days	Base line 0th day First follow up on 16th day 2nd follow up on 30th day
B	30	Convolvulus Pluricaulis oil nasal administration (*Shankhapushpi Taila Nasya)*	8 drops each Nostrils	15 days	Base line 0th day First follow up on 16th day 2nd follow up on 30th day

Study instruments

1. Ayurveda Texts
2. Modern texts
3. Online search- Google scholar etc.
4. Cow milk treated with Sida Cordifolia oil nasal administration
5. Ksheerbala Taila Nasya
6. Convolvulus Pluricaulis oil nasal administration
7. Shankhapushpi Taila Nasya
8. Case record form
9. Patient Information
10. Written and informed consent form

Drug collection/authentication: The raw drug will be procured from reliable sources and authenticated by Department of *Dravyaguna* and *Rasashastra* of Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Wardha.

Statistics outcome: After the study data will be analyzed according to a suitable statistical test.

Data Analysis: The collected data will be analyzed with the help of inferential statistical test.

Discussion

The three *Ayurvedic sthambhas—Vata*, *Pitta*, and *Kapha*—oversee all the body's essential processes. When the three *Sthambhas* are in an equilibrium state, a person is said to be healthy. There are three Pillars (*Upsthambha)* to support these *Sthambha.*

Food (Ahara), Sleep (*Nindra*) and Celibacy (*Brahmacharya*) are the three. *Upsthambha* is one of the main forces that contribute to and support life. Such Pillars (*Upsthambha)* increase the strength of an individual. Sleep (*Nindra)* has an impact on both mental and physical elements. Nidra is therefore crucial for both physical and emotional wellness.

Work, ageing, illnesses, constitution, and some Doshas like Vata and Pitta were only a few of the many causes of sleep deprivation that were explained by Ayurveda. These elements have a direct impact on sleep and result in sleep loss. Loss of sleep can occur for a variety of causes, including disease, stress, ageing, pain, mental illness, and others, according to modern scientific theory. Insomnia was included in the 80 *Vataja disease* by *Charaka* and *Kashyapa.*

The herb Convolvulus Pluricaulis (*Shankhpushpi)*, a memory enhancer *utilized* as a brain tonic to stimulate cognition and brain function. It improves focus and learning skills and aids in the treatment of conditions such as depression, stress, and mental tiredness.

The *Medhya* effect increases strength of mind, which helps one resist the pathophysiology of depression and anxiety and promotes restful sleep. Convolvulus Pluricaulis (*Shankhpushpi)* is said to improve the quality and length of natural sleep by lowering cortisol (the stress hormone) levels, which in turn reduces stress.

The chemical components of *Shankhpushpi*, including flavonoids kaempferol and phytosterols, myristic acids, scopoletin, -sitosterol, tetratriacontane acids, and convoline, aid to promote general health and prevent disease-related sleeplessness.

Since the nose serves as the brain's entrance, this procedure allows for the administration of medications in accordance with the severity of the patient's illness. It is a very effective therapy modality that is included in the arsenal of purification therapies due to the numerous classifications and varieties of nasal procedure that have been stated, as well as the various

methods of medication delivery. Following a thorough examination of the patient and the selection of a particular nasal procedure, pre-procedure, procedure, and post procedure can be readily carried out systematically. The method's likely mode of action indicates that it is successful in producing the desired effects in the treatment of insomnia.

Conclusion

Convolvulus Pluricaulis oil nasal administration may be more effective than cow milk treated with Sida Cordifolia oil nasal administration in treating insomnia while having fewer adverse effects.

Ethical consideration

The study will start after clearance from the IEC of Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod(H) Wardha. And after CTRI registration. Ref. No. MGACHRC/IEC/June-2023/707

The committee will decide on the endpoint and oversee the trial as it progresses.

Consent

Both written and verbal consent of the patient will be taken before conducting the trial in the local language while explaining every aspect of the study. The researcher will take consent from trial participants.

Dissemination

This protocol will be further published as a thesis to disseminate the study of Insomnia. The study protocol provides a detailed overview of the study design, methodology, data collection, data analysis plan, and ethical consideration. By disseminating this protocol, we hope to advance knowledge in the field of research.

Study status

We have started enrolling patients.

Ayurvedic Terminology and its translation

sr. no.	Ayurvedic terminology	Transaltion
01.	***Doshas***	One of three functional energies in nature: vata, pitta, and kapha. In the body, it is the unique ratio of these three humors that determines an individual's Prakruti (constitution). When the doshas are present in appropriate quantities, they support the health and integrity of the body; when they are out of balance, they can cause illness and disease.
02	***Vata***	One of the three doshas (functional energies in nature); vata is predominated by the ether and air elements and governs movement and communication; it is light, cold, dry, rough, mobile, subtle, and clear.
03	***Pitta***	One of the three doshas (functional energies in nature); pitta is predominated by the fire and water elements, and it governs transformation; it is light, sharp (or penetrating), hot, oily, liquid, and spreading.
04	***Rasa***	A Sanskrit word with many meanings, including "taste," "flavour," "essence," "experience," "juice," "sap," and "plasma." Ayurveda identifies six primary tastes: madhura (sweet), amla (sour), lavana (salty), katu (pungent), tikta (bitter), and kashaya (astringent). As a taste, rasa is our first experience of an ingested substance
05	***Virya***	The heating or cooling nature of an ingested substance, is experienced after rasa (taste), but before vipaka (the post-digestive effect); while there is a broad spectrum of variance between hot and cold, most substances can be described as being either heating or cooling in nature.
06	***Vipka***	The post-digestive effect of an ingested substance, is experienced in the final stages of digestion—after the rasa (taste), and virya (heating or cooling energy of a substance) have been experienced; this stage of digestion affects the excreta and nourishes the individual cells.

Data availability

No data as this is a protocol.

Reporting Guidelines

Figshare: - SPIRIT Checklist for study. Evaluation of Comparative Efficacy of cow milk treated sida cordifolia Oil Nasal Administration (*Ksheerbala Taila Nasya)* versus Convolvulus Pluricaulis Oil Nasal Administration (*Shankapushpi Taila Nasya*) in the Management of Primary Insomnia (*Anidra*). DOI: 10.6084/m9.figshare.24037839

References

1. Jaiswal YS, Williams LL: **A glimpse of Ayurveda–The forgotten history and principles of Indian traditional medicine.** *J. Tradit. Complement. Med.* 2017 Jan 1; **7**(1): 50–53.
PubMed Abstract | Publisher Full Text | Free Full Text
2. Peterson CT, Lucas J, John-Williams LS, *et al.*: **Identification of altered metabolomic profiles following a panchakarma-based ayurvedic intervention in healthy subjects: The self-directed biological transformation initiative (SBTI).** *Sci. Rep.* 2016 Sep 9; **6** (1): 1–4.
Publisher Full Text
3. Reference Source
4. Samhita C, Shukla AV, Pratishthan CS: **delhi. Edition- 2015. Sutra Sthana Chapter 21 Asthoninditiya Adyaah sloka 35.**
5. Samhita C, Shukla AV, Pratishthan CS: **delhi. Edition- 2015. Sutra Sthana 20 Asthodariya Adyaah sloka 11.**
6. Samhita S, Ambikadattashashtri A, Prakashan CS: **Varanasi. Edition-2007. Sharir Sthana Chapter 4 Garbhavyakaran Sloka 41.**
7. Hridayam A, Brahmanandtripathi CSP: **delhi, reprint edition- 2017. Sutra Sthana Chapter 7 Annaraksha Adhyaah Sloka 64.**
8. Reference Source
9. Kumar S, Patel D, Tiwari A, *et al.*: **A Review on Role of Shankhpushpi Kalka and Yashtimadhu Taila Shirodhara towards the Management of Anidra.** *Journal of Drug Delivery and Therapeutics.* 2019 Dec 6; **9**(4-A): 884–886.
10. Singh G: **Nasya Therapy-A Pharmacological Route for Drug Delivery to Brain.** *Journal of Ayurveda Physicians & Surgeons (JAPS) (EISSN 2394-6350).* 2018 Nov 6; **5**(3).
11. Shilpa SN, Krishnamurthy MS, Ravishankar B, *et al.*: **PRELIMINARY ANALYTICAL STUDY OF SAINDHAVADYA GHRUTA.** *Int. J. Ayur. Pharma Research.* 2014; **2**(4): 135–140.
12. Singh AK: **Manasika Bhavas in Anidra -Stress Induced Chronic Insomnia - Mamsyadi Ghrita - Dashamula Kwatha Shirodhara-Kc (Manasa)- 2007-Ipgt&Ra, Gau, Jamnagar.**
13. Ravindra A: **A text book of Bhaisajya Kalpana Vijnana [Pharmaceutical science], Chaukhamba Surbharati Prakashan-Varanasi, edition-2011.**
14. Reference Source
15. Reference Source
16. Bastien CH, Vallières A, Morin CM: **Validation of the Insomnia Severity Index as an outcome measure for insomnia research.** *Sleep Med.* 2001 Jul 1; **2**(4): 297–307.
Publisher Full Text
17. Flanagan JC: **A research approach to improving our quality of life.** *Am. Psychol.* 1978; **33**: 138–147.
Publisher Full Text
18. Samhita S, Ambikadattashashtri A, Prakashan CS: **Varanasi. Edition-2007. Chikitsasthan chapter 40/28.**

Open Peer Review

Current Peer Review Status: ✔ ✔

Version 1

Reviewer Report 09 February 2024

https://doi.org/10.5256/f1000research.152792.r216808

✔ **Anup Jain**
Charak Brahm Prakash Ayurved Charak Sansthan, Najafgarh, Delhi, India

The article requires thorough grammatical vetting and needs to be clear upon the status of obtaining the IEC and CTRI numbers if they have started the recruitment of patients. It will also be prudent to provide the basis on which superiority trial is being conducted, if any pilot study has been conducted on the efficacy of the trial drug to arrive at the exact sample size which is required for superiority trial. The author may also elaborate the method of blinding in the final work

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Ayurved, Panchakarma, Musculoskeletal, Neuromuscular and mental health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 09 February 2024

https://doi.org/10.5256/f1000research.152792.r216809

Manjusha Sunil More
Shree Saptashrungi Ayurved Mahavidyalaya and Hospital, Nasik, Maharashtra, India

- The need of the study is explained appropriately.
- Materials and Methods are found.
- Selection of drugs are justified with proper classical Ayurvedic References
- Plan of procedure and study design is formed correctly.
- The selected disease is really good.

Overall the work is good and may be beneficial for society.

Additional information to add: Scope of research, and upcoming research.

1. Maybe work by increasing the duration of treatment.
2. Maybe work by using the same protocol for other diseases.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.