



STUDY PROTOCOL

REVISED Evaluation of comparative efficacy of Mashadi oil
(*Tinospora cardifolia*) and Erandadi oil *Ricinus communis* via
nasal administration in the management of cervical
spondylosis: a randomized controlled trial protocol

[version 2; peer review: 1 approved with reservations]

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Abstract

Background- Cervical spondylosis is a disease that is caused by the vitiation of only one bodily humor (dosha) (Vataja nanatmaja). The vata bodily humor (dosa) becomes vitiated and settles in the cervical (many), creating neck pain and stiffness, which ultimately led to cervical spondylosis. Cervical spondylosis can be examined primarily under the generalization of cervical spondylosis because both conditions have many of the same symptoms. A disorder known as cervical spondylosis, which affects the cervical vertebra, is a degenerative condition of the cervical spine. In addition to having negative effects on a person's health, the disease also significantly lowers the quality of life and daily activities. Ayurveda suggested a treatment for cervical spondylosis to avoid and control the condition. There are numerous therapies in Ayurveda, and Oil administration through the nostrils has been given a significant role in upper clavicular disease (Uurdhvajatrugata roga). Oil administration through nostril therapy has been specifically recommended by Acharya Charka for the treatment of cervical spondylosis. The purpose of certain ayurvedic approaches in the management of cervical spondylosis.

Methods: - 60 patients will be split into two groups for this investigation. A *tinospora cardifolia* and a group of drugs (Mashadi oil) will be given to the group through the nostrils for seven days at a dose of eight drops. The same will be used for the other 30 patients, i.e., group B with *Ricinus Communis* and a group of drugs (Erandadi

Open Peer Review**Approval Status ?**

1

version 2

(revision)

20 Aug 2024

version 1

24 Jan 2024



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India

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

oil) administered through the nostrils.

Expected result: The result will be assessed on the baseline of objective parameters, and data will be compared after the treatment.

Keywords

Keywords – Cervical spondylosis, Oil administration through nostrils, Mashadi tail Oil administration through nostrils Erandadi tail Oil administration through nostrils.



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

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REVISED Amendments from Version 1

Revision and changes done in Protocol are as following:

1. Title was updated.
2. Rationale behind the Protocol was mentioned.
3. In Objective, we have clarified the primary and Secondary Objective.
4. Study instrument name added.
5. In Analysis part: Subjective and objective Analysis are clearly mentioned, separately now.
6. Methodology elaborated.
7. The criteria for discontinuing trial participants and strategies to improve adherence to intervention protocols and procedures for monitoring adherence are now mentioned clearly.
8. Clarification done regarding concomitant care and intervention that will be permitted or prohibited during the trial period.

Some more clarification regarding protocol:

1. Sample size calculation basis on the Mother Article.
2. Drug: we have mentioned all the content and properties of drug used in trial as tabular form.
3. Age group samples taken from mother article.
4. Study Site: Mahatma Gandhi Ayurveda College, hospital and Research center, Salod (H), Wardha, Maharashtra.

Any further responses from the reviewers can be found at the end of the article

Introduction

According to Acharya Charak,¹ 80 diseases are caused by the vitiation of only one bodily humor (dosa) (vataj nanatamaj) in Ayurveda. The cervical (Manya) is the locomotor portion. Cervical spondylosis (Manayahstambh) is caused by excessive driving, excessive travel, daytime sleep, and prolonged sitting and standing (in a fixed posture). In addition, the air (vayu) is covered by the kapha of the cervical vein (Manyagata Siras), which results in stiffness and pain in the neck, which in turn causes cervical spondylosis.² Pain and stiffness and restricted movements in human life are the two primary symptoms of cervical spondylosis.

In the current medical system, muscle relaxants, NSAIDs, analgesics, and corticosteroids are offered as the first line of treatment. The patient doesn't experience lasting relief, and long-term usage of these medications might have dangerous negative effects on patients.³

Cervical spondylosis is a common site for age-related neck spinal disk wear and strain. As a disk wears and compresses. When symptoms do show up, they include neck discomfort and stiffness. Sometimes, cervical spondylosis causes the space required by the spinal cord and the nerve root that passes through the spine to the rest of your body to shrink may encounter if the spinal cord or nerve roots are squeezed. Your arm, hand, legs, or feet may feel tingly, numb, or weak.⁴

Degenerative changes are visible in 25% of persons under the age of 40, 50% of people over the age of 40, and 85% of people over the age of 60. The levels that are most frequently impacted are C6-C7 and C5-C6. The prevalence of neck discomfort in the general population varies from 0.4% to 41.5% at the point, from 4.8% to 79.5% over a year, and from 0.4% to 86.8% during a lifetime. According to the Global Burden of Disease 2015 study, low back, and neck pain continue to be the leading cause of years spent with a handicap.⁵

Oil administration through the nostrils must be used as the initial kind of treatment in this situation. The upper neck areas are treated with Oil administration through the nostrils.⁶

Due to its progressive character, cervical spondylosis disease has grown into a serious hazard to the working population. While modern medicine offers a variety of medical and surgical treatments, it is evident that none of them are effective for cervical spondylosis. According to established science, all forms of treatment only temporarily relieve symptoms. As a result, Ayurveda is increasingly being considered for chronic diseases.⁸

Cervical spondylosis is a condition that is becoming more common today due to the use of computers, excessive cell phone use, and heavy weightlifting by the younger generation. This affects the cervical region and arm and results in symptoms like pain, stiffness, headaches, restricted movement, and loss of motor function in the arm because of increased Vata bodily humor (dosa), which is located in the cervical region.⁹ As a result, acharyas have mentioned vata kapha decrease (Vata kapha sama) Sneha drugs should be used in Oil administration through nostrils, and dry steam (Ruksha Sweda).¹⁰

मन्यास्तम्भेऽप्येतदेव बध्निनं, वशिषतो वातश्लेष्महरैरनस्यै रूक्षस्वेदैश्चोपचरेत्॥Su.chi.5/20

As stated by Acharya in “Nasa Hi Shiraso Dwaram,” enabling Oil administration through the nostrils Drug to enter the nasal route leads to Shringataka Marma and acts as the nursing the tissue (Dhatuposhana) and disease-free (Vyadhiharan) of the eye, ear, throat, etc.¹¹ Mashadi tail has shown to be effective in preventing Manyahstambh (cervical spondylosis), but it consumes more than Erandadi tail because it contains 12 medications compared to just seven. Ksheerpaka Vidhi prepares erandadi tail with milk (ksheer), which has a soft (Mridu) effect, is nutritious for the nervous system, and is enriched with calcium.¹² To compare the effectiveness of Eranda tail and Mashadi tail oil administration through nostrils in patients with cervical spondylosis, this study was conducted.

Rationale: Cervical spondylosis, a degenerative condition affecting the cervical spine, presents several challenges in modern medicine and physiotherapy. In Ayurveda, we manage the degenerative changes in the spine.

Aim

Evaluation of the comparative efficacy of *tinospora cardifolio* and a group of drugs (Mashadi tail Oil administration through nostrils) administered through nostrils and *Ricinus Communis* and a group of drugs (Erandadi Taila Oil administration through nostrils) in the management of Manyasthambha (Cervical Spondylosis).

Objective

Primary objective – Range of motion

- To evaluate the efficacy of Mashadi taila oil administration through nostrils over a range of motion in the management of cervical spondylosis.
- To evaluate the efficacy of erandadi taila oil administration through nostrils over range of motion in the management of cervical spondylosis.
- To compare the efficacy of mashadi taila oil administration through nostrils and erandadi taila oil administration through nostrils over the range of motion in the management of cervical spondylosis.

Secondary objective – VAS, Neck Disability Index

- To evaluate the efficacy of mashadi taila oil administration through nostrils over pain (visual analog scale) in the management of cervical spondylosis.
- To evaluate the efficacy of erandadi taila oil administration through nostrils over pain (visual analog scale) in the management of cervical spondylosis.
- To compare the efficacy of mashadi taila oil administration through nostrils and erandadi taila oil administration through nostrils over pain (visual analog scale) in the management of cervical spondylosis.
- To evaluate the efficacy of Mashadi taila oil administration through nostrils over neck Disability Index in the management of cervical spondylosis.
- To evaluate the efficacy of erandadi taila oil administration through nostrils over the neck disability index in the management of cervical spondylosis.
- To compare the efficacy of mashadi tail oil administration through nostrils and erandadi tail oil administration through nostrils over the neck disability index in the management of cervical spondylosis.

Protocol

Study setting

The patients would be chosen from the Mahatma Gandhi Ayurved College, Hospital & Research Center, Salad (H)'s Panchakarma OPD, and IPD. For the trial, a total of 60 participants gets enrolled. They will be divided into two teams. Group A uses Mashadi oil in the nostrils, while Group B uses Erandadi oil in the same way. At the beginning of the trial, all baseline parameters will be recorded. Both groups of patients will receive Oil administration through nostril treatment for seven days (Figure 1).

➤ Study design-

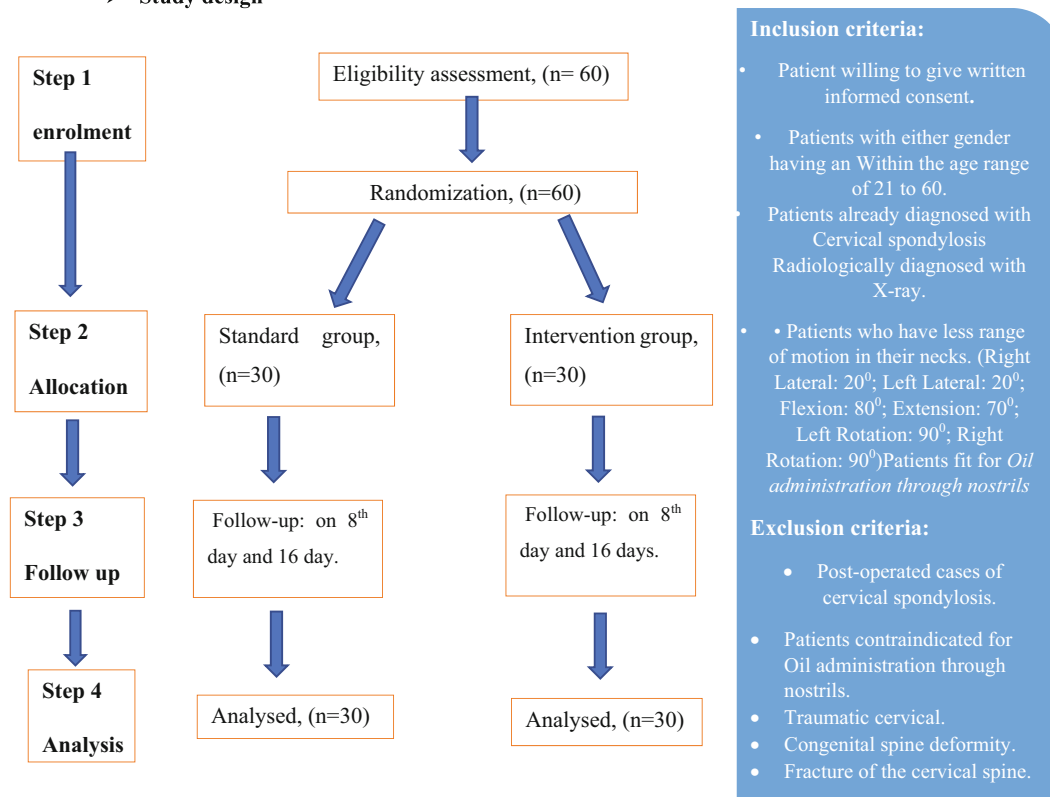


Figure 1. CONSORT flow chart.

Roles and responsibilities of committees: The study will start after clearance from the I.E.C. of Mahatma Gandhi Ayurveda College Hospital and Research Center, Salod (H.), Wardha. And after CTRI registration. Ref. No. CTRI/2023/03/050923. The committee will decide on the endpoint and oversee the trial as it progresses. The researcher will assess any adverse event and will be reported to the Ethics committee.

Guidelines – SPIRIT Guidelines are being used for the study.

Methodology

The randomized controlled trial will take place at Mahatma Gandhi Ayurveda College, Hospital, and Research Centre in Salod (H). Ethical approval has been granted by the Institutional Ethical Committee of DMIMS, Wardha, Maharashtra, India. The trial is registered with the Clinical Trials Registry-India (CTRI) under the number CTRI/2023/03/050923.

Case definition

A cervical spondylosis patient who has been diagnosed with patients who have impaired neck ROM. Patients of either gender who fall between the age range of 21 to 60 years (Right Lateral: 200, Left Lateral: 200, Flexion: 800, Extension: 700, Left Rotation: 900, Right Rotation: 900) are included in this study.

Sampling procedure – simple randomization. The researcher will enrol the participants, create the allocation sequence, and allocate them to the intervention.

Type of study – Interventional study

Study design – Randomized standard controlled double-blind superiority clinical trial.

The allocated intervention will blind participants.

Inclusion criteria

- Patient willing to give written informed consent.
- Patients with either gender and within the age range of 21 to 60.¹³ (Age group selected on the basis of mother article.)
- Patients already diagnosed with cervical spondylosis, radiologically diagnosed with X-ray.
- Patients who have less range of motion in the neck. (Right Lateral: 200; Left Lateral: 200; Flexion: 800; Extension: 700; Left Rotation: 900; Right Rotation: 900)
- Suitable patients for oil administration through nostrils (Figure 2).¹⁴

Oil administrated through the nostrils

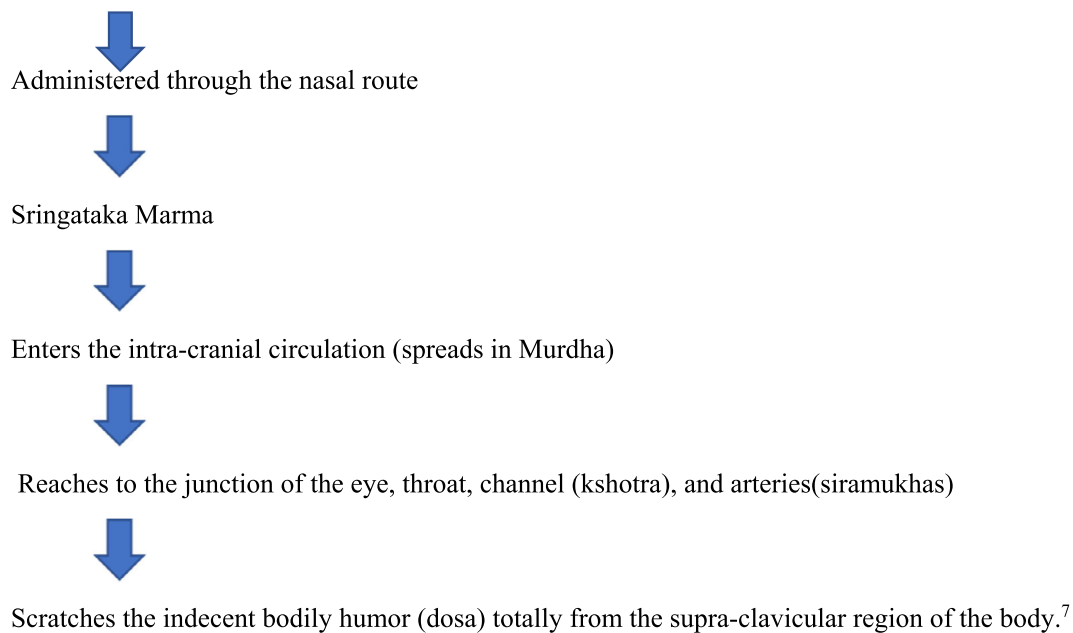


Figure 2. Mode of action of Nasya karma (oil administration through nose).

Exclusion criteria

- Post-operated cases of cervical spondylosis.
- Patients contraindicated for oil administration through nostrils.¹⁵
- Traumatic cervical spine.
- Congenital spine deformity.
- Fracture of the cervical spine.

> Study design-

Detail of drug preparation

Figure 3 shows preperation of Ricinus communis oil.



Figure 3. Flow chart showing the preparation of erandadi oil.

Drug Analysis are done in Dravyaguna Department

Preparation

*Oil administration through nostrilskarma Procedure*¹⁶ -

➤ Pre procedure (Poorvakarma)

Instruments (Sambar Sangraha): For *Oil administration through nostrils*, pick a space with sufficient lighting and no airborne contaminants like smoke or dust. Collect the required supplies for Oil administration through the nostrils, including a table or a chair, supplies for steam, medicine, a towel, cotton, a serving bowl, and oil.

Patient fit for the procedure (Aturasiddhata): To get oil administration through the nostrils, the patient's posture should allow him to lean comfortably returning to the backrest with his slightly arched neck. The patient should be forced to lie down on the oil administration through the nostrils with their head slightly tilted back and a towel placed under their neck. Perform face and head massages (Mukha and Shirbhyanga) with oil after that. Mild steam should be applied to the face and head after abhyanga. Even though providing Steam to the head is prohibited, light steam (Mridu Swedan) can be given to remove impurities and cause the bodily humor (dosa) to liquefy. After performing a sedan on the head, gently massage the neck and shoulders.

Table 1. Characteristics of drugs.

s. no.	Drug	Latin name	Rasa	Guna	Virya	Vipak	bodily humor (bodily humor (dosa)))ghana
1	Eranda	Ricinus communis	Madhura Katu kashaya	Snigdha Tikchana Sukchham	ushna	Madhur	Vata+kapha
2	Sinha phala	Solanum virginianum	Tikkata katu	Laghu Rukchha Tikchana	ushna	katu	Kapha+vata
3	Devdaru	Cedrus deodara	tikatta	Laghu Snigdha	ushna	katu	Kapha+vata

Table 1. *Continued*

s. no.	Drug	Latin name	Rasa	Guna	Virya	Vipak	bodily humor (bodily humor (dosa))ghana
4	vacha	Acorus calamus	Katu tikkata	Laghu Tikchha	ushna	katu	Kapha+vata
5	Tagar	Valeriana Wallachia	Tikata Katu kashaya	Laghu Tikcha	ushna	katu	Kapha+vata
6	vidanga	Embelia Ribes	Katu Kashaya	Laghu Rukchha Tikchha	Ushna	Katu	Kapha+Vata
7	Bela	Aegle marmelos	Kashaya tikatta	Laghu Rukchha	ushna	katu	Kapha+vata

➤ **Main procedure (*Pradhanakarma*)**

Once the patient is comfortable with their arms and legs extended, their head is lowered a bit, and their eyes are covered with a cloth. Then slowly pour eight drops of oil. Give the patient mild steam repeated on the cheeks, forehead, hands, and feet. after delivering oil administration through the nostrils. Then, continually tell the patient to spit the oil that entered their throat into a vessel. It is not advisable to swallow medicine that enters the digestive system.

➤ **After the procedure (*Panchakarma*)**

Give the patient warm water to rinse their mouth and throat after spitting the drug out of their throat. then counsel medicated smoke (*Dhoompana*) to rinse his mouth and throat so that the clear bodily humor (dosa) can leave. after waiting for five to ten minutes.

Intervention modification - Any negative side effects will have noticed and reported to the ethical committee. The harmful effect will be treated for the patients. The reason for ending the treatment shall be stated if participants choose to withdraw.

Outcomes - To compare the efficacy of *Mashadi tail Oil administration through nostrils and Erandadi tail Oil administration through nostrils* with criteria like Range of Motion, VAS, and Neck Disability Index.

Subjective Analysis – Neck Disability index.

Objective Analysis – VAS scale, Range of Motion.

A. Range of Motion¹⁶

Table 2. Range of motion.

MOVEMENT	NORMAL READING
Flexion	80°-90°
Extension	70°
Right Lateral	20°-45°
Left Lateral	20°-45°
Right Lateral	90°
Left Rotation	90°

Instrument – Goniometer

B. Visual Analogue Scale: -

On a scale of 0 (no pain) to 10 (worst pain), the patient will be asked to rate their level of discomfort (Figure 4).

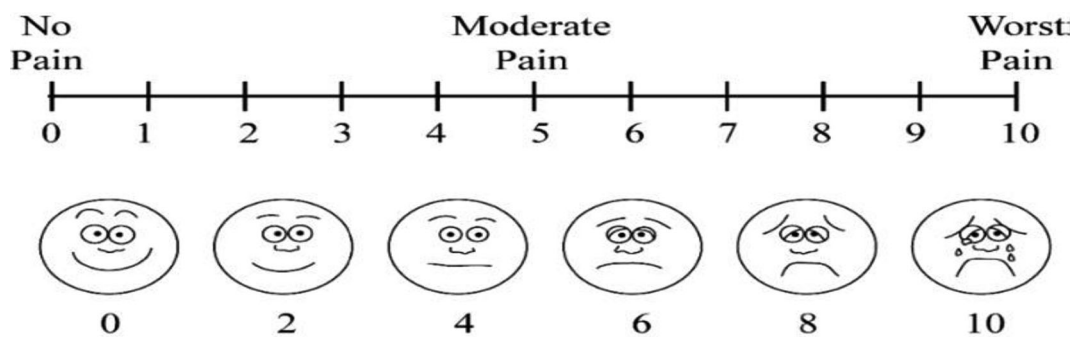


Figure 4. Visual analogue scale.

C. Neck Disability Index¹⁷

Neck Disability Index is a subject criteria variable's are mentioned in reference
Participant timeline

Table 3. Gantt chart.

Scholar/Investigator	Dr. Madhvi Jain					
Title	Evaluation of Comparative Efficacy of A Tinospora cardifolia and a group of drugs (Mashadi Taila Oil administration through nostrils) and Ricinus Communis and a group of drugs (Erandadi oil Oil administration through nostrils) administered through the nostrils in the Management of Cervical Spondylosis (Cervical Spondylosis)					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Approval from IEC						
Review of Literature						
Drug Preparation						
Enrollment of the patients						
Data Collection						
Statistical Analysis						
Thesis Writing						
The Submissions						

Sample size

Sample size calculate on the basis of Mother Article

Formula Using Mean Difference

$$1 = n2 = 2 \frac{(Z_{\alpha} + Z_{\beta})^2 \sigma^2}{(\delta)^2}$$

$$Z_{\alpha} = 1.96$$

$\alpha = \text{Type I error at } 5\% \text{ at both sides two tailed}$

$Z_{\beta} = 0.84 = \text{Power at } 80\%$

Primary Variable = Flexion (degree)

(Mean) value of flexion for Mashadi tail treatment group (Before) = 31.77 (As Per Reference article)¹⁸

(Mean) value of flexion for Mashadi tail treatment group (After) = 50. (As Per Reference article).

Mean Difference for the effect in flexion after & before $50 - 31.77 = 18.23$

Standard Deviation = 3.821 (As Per Reference article)

Considering 15% clinically relevant margin for experimental group (δ) = $(18.23 * 15)/100 = 2.7345$. $n_1 = n_2 =$
 $2 \frac{(1.96 + 0.84)^2 (3.821)^2}{(2.7345)^2} = 30 \text{ per group}$

Considering 10% drop out = 3

Total sample size required = $30 + 3 = 33$ per group.

Recruitment

The Mahatma Gandhi Ayurveda College, Hospital & Research Center, Salod (H), Wardha Maharashtra will choose patients for Cervical Spondylosis from the OPD and IPD of Panchakarma. For the trial, a total of 60 participants will be enrolled.

Allocation sequence generation – computer-generated random numbers.

Allocation implementation – Participants will be enrolled, given an intervention, and given an allocation sequence by the researcher or the original author.

Blinding – double-blind superiority clinical trial.

Study instruments

1. Ayurveda Samhitas
2. Modern texts
3. Online search- Google Scholar, etc.
4. Mashadi tail Oil administration through nostrils
5. Erandadi tail Oil administration through nostrils
6. Case record form
7. Patient information
8. Written and informed consent form
9. Measuring scale
10. Sphygmomanometer
11. Goniometer
12. Nasal dropper

Data collection plan

Table 4. Posology.

Group	Sample size	Intervention	Dose	duration	Follow up
A (control group)	30	<i>Mashadi Taila Oil administration through nostrils</i>	8 drops in each nostrils daily	Seven days	Baseline assessment- Day 0 1st Follow-up – 8 th day 2nd Follow-up – 16 nd day
B (Intervention group)	30	Erاندادی Taila Oil administration through nostrils	8 drops in each nostril daily	Seven days	Baseline assessment- Day - 0 1st Follow-up – 8 th day 2nd Follow-up – 16 nd day

Study Plan: The study includes two groups, A and B, each consisting of 30 participants. Group A, the control group, will receive Mashadi Taila oil administered through the nostrils, with 8 drops in each nostril daily for seven days. The baseline assessment for Group A will be conducted on day 0, the first follow-up on the 8th day, and the second follow-up on the 16th day. Group B, the intervention group, will receive Erاندادی Taila oil administered through the nostrils, with 8 drops in each nostril daily for seven days. The baseline assessment for Group B will also be conducted on day 0, the first follow-up on the 8th day, and the second follow-up on the 16th day.

Concomitant care and intervention: In cases of severe pain, we use NSAIDs and withdraw the patient from the study.

Drug collection/authentication

The department of Dravyaguna and Rasashastra of M.G.A.C.H. and RC, Salod, Wardha will validate and identify the drug's raw material before it is obtained from a trustworthy source.

Statistics outcome

Following the study, the data will be examined using the appropriate statistical test.

Data Analysis (Statistical Methods)

An inferential statistical test will be used to examine the acquired data.

Discussion

Cervical Spondylosis is a condition that affects the cervical area. Pain, stiffness, and limited cervical movement are some of its symptoms. One of the panchakarma procedures is Oil administration through the nostrils, which involves applying medicated oil, decoction (qwath), and buttermilk (Gruta) through the nose. For a total of seven days, the 30 patients undergo Masahdi Tail Oil administration through nostrils (8 bindu in each nostril).

Conclusion - Erاندادی oil nasal administration may be more effective than Mashadi oil nasal administration in treating Cervical Spondylosis while having fewer adverse effects.

Ethical consideration – After receiving approval from the I.E.C. of the Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod(H), the study will begin. also following CTRI registration. No. of reference CTRI/2023/03/050923

The committee will select the trial's endpoint and monitor its execution.

Any negative incident will be evaluated by the researcher and submitted to the ethics committee.

Consent - Before starting the studies, the patients' agreement will be obtained after a thorough explanation of the study's objectives. Trial participants' consent will be obtained by the researcher.

Providing patients with medical services, medications, or treatments to improve their health.

If a patient discontinues treatment, it is considered a withdrawal.

Before, during, and after the experiment, the participants' private information will be gathered and maintained in confidence. The researcher will be the only person with access to the physical data, which will be maintained in a safe place. Computerized data will be stored on a password-protected hard drive that will only be accessible to the researcher.

Dissemination – This protocol will also be made available as a thesis to spread the word about the research for cervical spondylosis. A thorough explanation of the study's methodology, data-gathering techniques, data-processing strategy, and ethical considerations is provided in the study protocol. We want to increase the body of knowledge in this area and make it easier for future studies by spreading our procedure.

Study status - Now we are in the screening phase of the patients for the above study.

Reporting guidelines

Zenodo. SPIRIT Checklist for study. DOI: <https://doi.org/10.5281/zenodo.8173935>.

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Data availability

No supporting information is available for this article.

Acknowledgments

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Open Peer Review

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Reviewer Report 21 June 2024

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Vineeta Kumari Negi

Regional Ayurveda Research Institute- CCRAS, Himachal Pradesh, India

Title: Instead of *Tinospora cordifolia* & *Ricinus communis* write the name of both the oils, as TC & RC are just one of the contents/ingredients of both the types of oils. Write according to PICOT.

Rationale: Not mentioned.

Objectives: Fewer the better, not mentioned which is your primary objective & which is your secondary objective. As sample size calculation is usually based on your primary objective.

Sample Size Calculation: What is the basis of sample size calculation? Usually we calculate the sample size on the basis of Primary Objective.

Drug: One should have Content of Drug Analysis/oil to be used in trial, therefore elaborate on this.

Age Group of samples; If it is Cervical Spondylosis then it is a degenerative disease, then how would you justify for the age of 20's.

Study Instruments & variables: Clearly define it.

Analysis Part: "depends on objective & study plan" therefore clearly define your objectives and study plan.

Study site: should be appropriate/ choose one site

Methodology: Elaborate it

Few more things: Please mention the criteria for discontinuing trial participants and strategies to improve adherence to intervention protocols and procedures for monitoring adherence.

Please clarify regarding concomitant care and intervention that will be permitted or prohibited during the trial period.

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

No

Is the study design appropriate for the research question?

Yes

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

Partly

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

No

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Musculoskeletal disorders, Anorectal disease 9eg Haemorrhoids, Fistula, Sinus), Pain management, Wound management.

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, however I have significant reservations, as outlined above.

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