

# Comparative Evaluation of Effective Route of Administration of MASAM Oil in *Vishwachi* (Cervical Radiculopathy): A Study Protocol

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## Abstract

**Background:** Ayurveda proposed a lot of *Vatavyadhi* treatments. The cervical problems mimic the disorders in the *vata*. Thus in the present study, the *vata* management of medicated oils by rectal is better management for the identified clinical condition *Vishwachi* (Cervical Radiculopathy). Among such disorders Ayurvedic classics in the name of *Vishwachi* have described a disease. In Harrison's Principles of Internal Medicine and Davidson's Principles of Internal Medicine and Golwalla Medicine for Students, the symptoms of Cervical Spondylosis with Radiculopathy, such as a neck pain that radiates to the upper limbs, restricted movements of the neck have been explained. Due to today's modern lifestyles, food, behaviors, stress and anxiety, more people face these problems and the incidence of the *Vishwachi* disease increases dramatically everywhere.

**Aim and Objectives:** To evaluate and compare the effect of MASAM oil for improving the Nerve Conduction Velocity in patients of *Vishwachi* (Cervical Radiculopathy) and to compare the MASAM oil through different routes of administration (*Pana*, *Abhyanga*, *Basti*) for improving Nerve Conduction Velocity in patients of *Vishwachi* (Cervical Radiculopathy).

**Methodology:** The proposed study, 120 subjects will be randomly divided into three groups in every group 40 patients will be including. In Group A (*Pana*) –with MASAM OIL dose of 24 ml will be administered orally a day in empty stomach for 21 days and Group B (*Abhyanga*) – local massage on affected side with MASAM OIL dose of 24 ml a day at morning after breakfast for 21 days and Group C (*Basti*) MASAM OIL 24 ml a day will be administered through rectal route after meal for 21 days. The record of assessment will be taken at zero day 21<sup>st</sup> day and after 21<sup>st</sup> for followup.

**Results:** On the basis of objectives outcome changes will be observed. Changes will be observed in objective outcomes.

**Conclusion:** It may conclude that the parameters included in this study will be reducing pain, tingling sensation and improvement in Nerve conduction parameters.

**Keywords:** *Vishwachi*, *Matrabasti*, *Abhyanga*, *Pana*, *Nerve Conduction Study*, *Cervical radiculopathy*.

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## Introduction

Cervical Radiculopathy disease occurs if an irritated nerve in the neck enters the spinal canal. Cervical radiculopathy, commonly known as “pinched nerve,” is typically a herniated disk or spur of the bone that

pushes the inflamed nervous root into one. These are usually a consequence of degenerative neck changes. The significant cause of neck pain and disability may be cervical radiculopathy (CR). 83.2/100.000 people report an annual CR incidence<sup>[1]</sup> while the reported prevalence is 3.5/1000 persons<sup>[2]</sup>. In today's world, cervical radiculopathy is more common with more cervical problems. We are used to electronic and/or work-related instruments. Therefore it is not possible to avoid it and to find a better healing area. The characteristic of *Vishwachi* may be correlated with cervical radiculopathy. Under *vatavyadhi* (disorders of *vata*), *Vishwachi* is identified because *Vishwachi* can be explained as disease starting from posterior part of hand and *prakoshtha*, hands, and fingers, manifest due to flexion and extension of the nerves which gives strength for the movements<sup>[3]</sup>. Ayurveda proposed a lot of *Vatavyadhi* treatments. The *vata* conditions are imitated by cervical problems. Therefore, the *vata* management of orally, rectal and surface (external) medicated oils is better controls in the current study of the clinical condition of *Vishwachi* (Cervical Radiculopathy).

**Rationale of the study:** *Vata* diseases are commonly expressed in musculoskeletal and neurological disorders. The selected disease condition *Vishwachi* is a neuro-musculoskeletal disorder. The nerve conduction test or demyelination and degeneration are not attributed to *vatavyadhi* with any measurable parameters. As there were no studies in relation are found to determine the nerve conduction in terms of *vata* here an attempt is made to evaluate and compare the effect of MASAM oil through *Basti*, *Pana* and *Abhyanga* for the improvement of nerve conduction. The main *Chikitsasutra* (principle) of *Vatvyadhi* is *Pana*, *Abhyanga* and *Basti*<sup>[4]</sup>. Yet, this tool of Nerve Conduction Velocity study didn't use in Ayurvedic research. There are no such evidences in *Vishwachi* (Cervical Radiculopathy) regarding Nerve Conduction Velocity (NCV)

Hence, we selected NCV studies to find out the better route of administration and effectiveness of MASAM oil in *Vishwachi* (Cervical Radiculopathy).

## Aim and Objectives

**Aim:** To evaluate and compare the effect of MASAM oil for improving the Nerve Conduction Velocity in patients of *Vishwachi* (Cervical Radiculopathy).

### Objectives:

1. To evaluate the effect of MASAM oil for improving Nerve Conduction Velocity in patients of *Vishwachi* (Cervical Radiculopathy).
2. To compare the MASAM oil through different routes of administration (*Pana*, *Abhyanga*, *Basti*) for improving Nerve Conduction Velocity in patients of *Vishwachi* (Cervical Radiculopathy).

**Case Definition:** A diagnosed *Vishawachi* subject with *Bahuprusthatha* symptoms (the back aspect of the upper limb) and with tingling sensation to the left or right, along with positive spurling test and a cervical distraction test along with range of motion.

**Research Question:** Whether MASAM Oil through different routs of administration (*Pana*, *Abhyanga*, *Basti*) is effective in improving Nerve Conduction Velocity in patients of *Vishwachi* (Cervical Radiculopathy)?

**Research Hypothesis:** MASAM oil is effective in *Vishwachi* (cervical radiculopathy) because of its composition qualities.

**Null Hypothesis:** There is no effect on MASAM oil in *Vishwachi* (cervical radiculopathy).

**Study Type:** Interventional

**Trial Design:** A Randomized Comparative clinical trial.

## Methodology

**Place of Study:** This study will be plan in M.G. Ayurved College Hospital & RC Wardha.

**Registration Number:** CTRI/2020/01/023022.

Composition of the trail drug: MASAM (Manjishta, Ashwgandha, Sahachar, Atmagupta, Masha) oil

**Table no. 1 Contents of MASAM oil**

Sno	Sanskrit name	Botanical name	Parts used	Quantity
1	Manjishta	Rubia cordifolia Linn	Root	1 part
1.	Masha	Vingna Mungo	Seed	1 part
2.	Atamagupta,	Mucuna pruriens Hook	Seed, root, pod hair.	1 part
3.	Sahachar	Barleria prionitis	Panchanga,leaf	1 part
4.	Ashwagandha	Withania somnifera	Root	1 part
6	Til	Sesamum indicum.Linn	Seed,oil,leaf,root	4 part

**Eligibility Criteria:** A 20 yrs to 60 years of both sexes, A diagnosed *Vishawachi* subject with Cervical compression.

Diabetic neuropathy, Post operated cervical radiculopathy and Indicated for Surgery and Severe giddiness and loss of function are excluded.

**Table no. 2. Interventions table**

Group	A	B	C
Sample size	40	40	40
Intervention	Abhyanga	Pana	Basti
Dose	24 ml	24 ml	24 ml
Duration	21 days	21 days	21 days
Follow up period	21 day	21 days	21 days
Total duration	42 days	42 days	42 days

**Criteria for discontinuing or modifying allocated interventions:** Subject will be pulled back from the investigation if any untoward rate, highlights of medication affectability or some other malady or issue emerges, Free treatment will be offered to the patients till the issues dissolves.

**Follow up:** After 21 days

**Primary Outcomes:** We will observe the efficacy of MASAM oil through *Pana*, *Basti* and *Abhyanga* on pain and tingling sensation before and after management. Data will be expressed as mean and standard deviation at 5% significance level. It may assumed that MASAM oil will be more effective through *Pana*, *Basti* or *Abhyanga* and we will compare the effect between the *Pana*, *Basti* and *Abhyanga* in pain, tingling sensation with no any adverse effects.

**Secondary Outcomes-** We will see the effect of

MASAM oil through *Pana*, *Basti* and *Abhyanga* on Nerve Conduction Parameters like Latency, Amplitude and Velocity.

## Discussion

Numerous studies established for *vata*vyadhi like *Panchakarma* procedure and shaman *chikitsa* too. The essential driver of cervical radiculopathy is age-related degeneration. In any case, there are a few special cases where spinal wounds to the plate can enlarge the degenerative procedure in the more youthful patient. An optional appearance of spondylosis is identified with the pressure of the vascular and neural structures brought about by a misfortune in the plate tallness and impinging osteophytes that add to the deadness, stun like sensations, pain, and interminable motor and tangible effects, which if not revised may prompt lasting incapacities<sup>[5]</sup>. Local application of MASAM oil may help to correct the *vata* vitiation. Moreover according to Ayurveda pain was caused by because of *vata* vitiation. All drugs have property of *vatahara* (anti inflammatory) and all drugs have property of nerve protector or working as a nervine tonic. So selected for this study.

**Manjishta**-is Anti-inflammatory, antioxidant<sup>[6]</sup>. **Aatmagupta**-is Neuro-protective and Neuro-restorative<sup>[7]</sup>. L-DOPA characterized by a deficiency in the synthesis of the neurotransmitter dopamine in nerve cell<sup>[8]</sup>. **Sahachar** -is commonly used in Neurological disorders and *vatakaphahara*<sup>[9]</sup>. **Masha**-is Anti-inflammatory and Nervine tonic<sup>[10]</sup>. The response involved in inflammatory as complex array of enzyme activation, mediator release, cell migration, fluid extravasations, tissue breakdown and repair. **Ashwagandha**-is Neuroprotective, Immunomodulatory and Anti - inflammatory.

**Statistical analysis:** Data will be analysed on the basis of appropriate statistics paired unpaired test and ANOVA by using SPSS software.

**Time duration till follow-up:** The treatment duration for the patients is 21 days and after that follow-up for 21 days.

**Followup period:** 0 day, 21 day and followup 21 day

**Time schedule of enrolment, intervention:** *Matrabasti, Pana and Abhyanga*

**Recruitment:** 40 (every group) sample recruited by single randomizing sampling.

**Method:** Literature review search, plane of work, Blue print in the form of flow chart, preparation of medicine, Data collection, treatment and its effect, will be observe which route of administration is best and statistical analysis.

**Data collection Method:** Randomized sampling

**Objective Criteria:** Assessment of numerical pain scale, neck disability index, cervical distraction, range of motion, Nerve conduction velocity, all the variables will be assessed before and after intervention of different route of administration.

**Data management:** The data coding will be done by principle investigator.

**Statistical Method:** Paired and unpaired for objective criteria, non parametric for subjective criteria, ANNOVA for comparing between three groups.

**Ethics and dissemination:** Research ethical approval: After critical evaluation and presentation the ethical committee has approve the research topic reference No – DMIMS (DU)/IEC/2018 -2019/7352.

**Consent assent:** Patient will be given detail information regarding intervention in his own language. Then written consent will be taken from patients before starting the study.

During study the confidentiality will be maintain.

**Dissemination policy:** The data will be spreading in the form of paper publication and Monograph. Authorship eligibility guidelines and any intended use of professional writers

**Informed consent materials:** Patient will be given all consent material in the form of hard copy, and related documents will be given to the participants.

**Strengths:** MASAM oil will be work for the nerving tonic and to find out best route of administration. If projected work results in the positive outcome then it will be established new mode of management for the cervical radiculopathy.

**Limitation:** Specific geographical area, convincing the patients for Nerve conduction study.

## Conclusion

Conclusion will be mentioned after the deliberate and analyzing data.

**Ethical Clearance:** Taken from institutional ethics committee.

**Source of Funding:** Self.

**Conflict of Interest:** Nil.

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