

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *ERANDADI TAILA* *KARNAPOORNA* ALONG WITH *GOGHRITPANA* IN THE MANAGEMENT OF *KARNA* *BADHIRYA* (SENSORINEURAL HEARING LOSS)

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How to cite this Article: *¹Dr. Ritu Kumari, ²Prof. Dr. Manoj Kumar, ³Prof. Dr. Ashu (2026). A Clinical Study To Evaluate The Efficacy Of Erandadi Taila Karnapoorana Along With Goghritpana In The Management Of Karna Badhira (Sensorineural Hearing Loss). World Journal of Pharmaceutical and Medical Research, 12(8), 291-295.

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Article Received on 04/07/2026

Article Revised on 25/07/2026

Article Published on 01/08/2026

ABSTRACT

Shira is the part of the body where life along with sense faculties resides. There are five *Gyanendriyan* (*Shira* sense organs) mentioned by our *Acharyas*. Among them, the functional aspect of hearing is “*Shravanendriya*”. The seat of *Shravanendriya* is *Karna*. Hearing is an important medium, which keeps one connected to other and with the surroundings. Hearing impairment (~*Badhira*) means complete or partial loss of the ability. According to *Acharya Sushruta*, vitiated *Vata dosha* along with *Kapha dosha* in *Sira* (~vein) occupies *Shabdanuvaha Sira* (~auditory nerve) in *Shrotrendriya* (~organ of hearing), leads to *Srotorodha* (~obstruction of channels), and further ignorance of this condition leads to *Badhira*. However, vitiated *Vata* is the cause of *Badhira*, according to *Madhavakara* and *Vidya*. *Vata Dosha Pradhan Badhira* can be correlated with Sensory Neural Hearing Loss (SNHL). SNHL is a type of hearing loss in which the root cause lies in the inner ear or sensory organ (cochlea and associated structures) or the vestibulocochlear nerve (cranial nerve VIII). It is estimated that over 60% of such hearing loss could be avoided through preventive measures. Ayurvedic management in *Badhira* is based on *Vatavyadhi Chikitsa Vidhi* (~neuroprotective treatment) and *Rasayana Chikitsa* (~rejuvenation therapy). These principles probably help in regeneration and repair of damaged hair cells which leads to improved hearing. This present study is planned to evaluate the efficacy of *Erandadi Taila Karnapoorana* along with *Goghritpana* in management of *badhira* (SNHL). A clinical single arm study containing 30 patients receive *Erandadi taila* along with *Goghritpana* to establish an effective ayurvedic management for SNHL.

KEYWORDS: *Karna Badhira*, Sensorineural hearing loss, *Karnapoorana*, *Vatavadhya*, *Rasayana chikitsa*.

METHODOLOGY: 30 patients of *Karna Badhira* will be selected on the basis of inclusion and exclusion criteria. All patients will be receiving three sitting of with *Erandadi Taila karnapoorana* with *Goghritpana*. Observations will be done on the basis of before, and after subjective and objective parameters.

INTRODUCTION

Shira is the part of the body where life along with sense faculties resides.^[1] There are five *Gyanendriyan* (*Shira* sense organs) mentioned by our *Acharyas*². Among them, the functional aspect of hearing is “*Shravanendriya*”. The seat of *Shravanendriya* is *Karna*³. Hearing is an

important medium, which keeps one connected to other and with the surroundings. Hearing impairment (~*Badhira*) means complete or partial loss of the ability. According to *Acharya Sushruta*, vitiated *Vata dosha* along with *Kapha dosha* in *Sira* (~vein) occupies *Shabdanuvaha Sira* (~auditory nerve) in *Shrotrendriya* (~organ of hearing), leads to *Srotorodha* (~obstruction of channels), and further ignorance of this condition leads to *Badhira*.^[4]

स एव शब्दानुवाह यदा सिराः कफानुयातो व्यनुसृत्य तिष्ठति ।

तदा नरस्याप्रतिकारसेविनो भवेत्तु बाधिर्यमसंशयं खलु ॥ सु. उ. (२०/८)

However, vitiated Vata is the cause of *Badhira*, according to *Madhavakara* and *Videha*. *Vata Dosha Pradhan Badhira* can be correlated with Sensory Neural Hearing Loss (SNHL). SNHL is a type of hearing loss in which the root cause lies in the inner ear or sensory organ (cochlea and associated structures) or the vestibulocochlear nerve (cranial nerve VIII). It is estimated that over 60% of such hearing loss could be avoided through preventive measures. Ayurvedic management in *Badhira* is based on *Vatavyadhi Chikitsa Vidhi* (~neuroprotective treatment) and *Rasayana Chikitsa* (~rejuvenation therapy). These principles probably help in regeneration and repair of damaged hair cells which leads to improved hearing.

AIM AND OBJECTIVES

Aim

To evaluate the efficacy of *Erandadi Taila Karnapoorna* along with *Goghritpana* in the management of *Karna Badhira* (SNHL)

Primary Objective

To evaluate the efficacy of *Erandadi Taila Karnapoorna* along with *Goghritpana* in the management of *Karna Badhira* (SNHL)

Secondary Objective

To study the *Karna Badhira* from various Ayurvedic texts.

Research Question

Is there any effect of *Erandadi Taila Karnapoorna* along with *Goghritpana* in the management of *Karna Badhira* (Sensorineural Hearing Loss)?"

Hypothesis

Null Hypothesis (H_0)

Erandadi Taila Karnapoorna along with *Goghritpana* are not effective in the management of *Karna Badhira* (Sensorineural Hearing Loss).

Research Hypothesis (H_1)

Erandadi Taila Karnapoorna along with *Goghritpana* are effective in the management of *Karnabadhira* (SNHL).

MATERIAL AND METHODS

To fulfil the aim and objectives, the study plan is divided into two sections. Literary Review

Clinical Study

Study Design

Type of Trial: Interventional Design: Randomized clinical trial Purpose: Treatment
Masking: No, Open Label Timing: Prospective Endpoint: Efficacy and safety Duration of trial: 65 days
Phase of trial: Phase 2 Subjects: 30
Statistical tool: Appropriate tool will be applied

Selection of Patients: A total of 30 patients meeting the

inclusion criteria were selected for the study from OPD & IPD of Shalaky Tantra Department. These patients were randomised into two groups, each consisting of 35 patients.

Inclusion Criteria

- Patients in the age group 16-60 years irrespective of age, sex, caste, religion etc.
- SNHL greater than 25dB and less than 70 dB with history less than one year.

Exclusion Criteria

- Age: - below 16 years and above 60 years
- Degree of hearing loss greater than 70 dB
- Conductive deafness
- Mixed hearing loss
- Middle ear pathology
- Inner ear pathology like acoustic neuroma, Meniere's disease.
- Genetic SNHL
- Syphilis SNHL
- Psychogenic hearing loss
- Systemic diseases: e.g. Diabetes, Hypothyroidism, Renal disorders, Autoimmune disorders, Multiple sclerosis.
- Malignancy.
- Pregnant women
- Head injury or injury to ear
- History of intake of ototoxic drugs
- Patient who needs surgical intervention

Investigations

Hematological and urine analysis will be carried out before treatment to rule out any systemic disease.

1. Hematological Examinations: Hb%, CBC (Complete blood count)
2. RBS [Random Blood Sugar]

Sources of Data

Literature Source: The literature related to disease, and the formulation will be reviewed from *Samhitas*, contemporary system of medicine textbook, published articles, research journals and relevant websites.

Clinical Source: Daily OPD, IPD patients of Institute for Ayurved Studies & Research Hospital, Kurukshetra & patients diagnosed as Cervical Erosion will be considered for the study after obtaining written informed consent.

Experimental Source: This was a human clinical study, no animal experimentation was conducted.

Intervention

	Treatment	Duration	Route of administration	Dose
Single group	Erandadi Taila	35 days (Approx. 2.5-3 min daily)	Karna	Till External acoustic meatus fills
	Goghritpana	35 Days HS	orally	20 ml

Route of Administration: local & oral application.

Method Of Karanpoorana Application

The whole procedure will be done in three steps after taking informed written consent, proper examination and investigations of patient.

Agnikarma procedure divided into 3 parts

1. *Purva karma*
2. *Pradhana karma*
3. *Pashchata karma*

1. Purva Karma

Prerequisites: Patient will be explained about the Karnapoorana Procedure & after that Informed and Written Consent will be taken.

Linen: Sterile gloves, Sterile gauze pieces, Sterile *Pichu*.

Instruments: Autoclaved dropper.

Others: Autoclaved *Ernadadi taila*.

2. Pradhana Karma

- Using a dropper, 10 drops of the warm medicated oil were gently instilled into the ear canal.
- The patient remained in the same position for about 3 minutes to allow the oil to penetrate deeply.
- A gentle massage was given around the ear and the adjacent area to facilitate the absorption of the oil.

3. Pashchata karma

- The residual oil was carefully wiped off from the outer ear using a sterile cotton swab.
- The ear canal was not flushed or cleaned aggressively to retain some of the beneficial oil.
- The patient was advised to rest for a few minutes after the procedure.
- They were advised to avoid exposure to cold air or water for a few hours post-procedure.

Post Procedure Precautions

- Ensured the oil was not too hot to avoid burning the delicate ear tissues.
- Maintained a sterile technique to prevent infections.
- Monitored the patient for any adverse reactions or discomfort during the procedure.
- Tailored the treatment according to individual patient needs and responses.

Karna Purana Vidhi was a traditional and effective

Ayurvedic procedure for treating ear ailments, including sensorineural hearing loss. Proper execution of the procedure, along with post-procedure care and follow-up, ensured optimal therapeutic outcomes and enhanced the patient's quality of life.

Follow up: 15th, 30th day.

Assessment Criteria**SUBJECTIVE**

- Difficulty understanding speech.
- Problems in conversations, particularly with more than one person.
- Turning up the TV and Radio volume to unreasonable high levels.
- Perceiving muffled sounds or ringing in the ears.

1. Ability to understand speech

- 1 – No significant difficulty understanding speech
- 2 – Mild difficulty understanding speech
- 3 – Moderate difficulty understanding speech
- 4 – Significant difficulty understanding speech

2. Communication with others

- 1 – No problems following conversations.
- 2 – Occasional problems following conversations, especially in noisy environments.
- 3 – Frequent problems following conversations, particularly with multiple people.
- 4 – Consistent problems following conversations, especially in groups.

3. Listening radio /TV

- 1 – Normal TV and radio volume
- 2 – Slight increase in TV and radio volume.
- 3 – Noticeable increase in TV and radio volume.
- 4 – High TV and radio volume. Total score = 12

Score > 6 = hearing difficulty present

Score <6 = hearing difficulty absent

Karnanada (tinnitus)

Grade	Stage of Tinnitus	BT	AT
0	No sound heard		
1	Only heard in quiet environment, no interference with sleep or daily activities.		
2	Occasionally interference with sleep but not daily activities.		
3	Maybe noticed even in the presence of background or environmental noise although daily activities may still be performed.		
4	Almost always heard, rarely if even masked leads to disturbed sleep pattern.		

OBJECTIVE

1. Tuning Fork Test-

- Rinne Test
- Webber Test

2. Audiometry – Pure Tone
Audiometry (SNHL)

0 to 25 dB – Normal hearing. 26 to 40 dB – Mild deafness.

41 to 55 dB – Moderate deafness.

56 to 70 dB – Moderately Severe deafness. 71 to 90 dB- Severe deafness

Above 90 dB- Profound deafness.

Scoring will be given on the basis of PTA findings.

General Symptoms	Score	Hearing Loss
Absence of Signs and Symptoms	0	0 to 25 dB
Presence of Signs or Symptoms in Mild degree.	1	26 to 40 dB
Presence of Signs or Symptoms in Moderate degree.	2	41 to 55 dB
Presence of Signs or Symptoms in Severe degree.	3	56 to 70 dB

Outcomes

- Primary – Improvement in hearing ability as per WHO Classification.
- Secondary – Improvement in quality of life of patient.

Sample Size

- Sample size is calculated on the basis of proportion of complete remission after therapy in two treatment groups using the formula.

$$n = \frac{Z^2 p(1 - p)}{e^2}$$

- Where n is the required sample size.
- Z is the Z-score corresponding to confidence level. For a 90% confidence level, Z is approximately 1.645.
- Ref- (https://www.researchgate.net/publication/358212809_Prevalence_of_hearing_loss_in_India)
- p is the estimated prevalence of tinnitus in the population, which is 0.07 (since 7% prevalence means p = 0.07).
- 1-p is the complementary probability, which is 1 – 0.07 = 0.93
- E is the margin of error, which is 0.08 (8%).

Plug these values into the formula- n =

$$\frac{(1.645)^2 \times 0.07 \times 0.93}{(0.08)^2}$$

- Now, n= 27.51515 (approx. 28)
- The minimum sample size to be calculated as n= 28

using LAMA approx. 30 cases will be taken.

Ethical clearance & CTRI Registration

The study was registered with the Clinical Trials Registry of India (CTRI) with **CTRI NO. CTRI/2025/04/083766**.

OBSERVATIONS AND RESULTS

The results were evaluated based on the predefined assessment criteria and statistically analysed for significance.

DISCUSSION

The obtained results will be discussed on the basis of Ayurvedic concept and modern parameters.

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