

Evaluation of Two Routes of Administration of *Carthamus tinctorius* as an Adjuvant Therapy with Standard Care and Physiotherapy in Thrombolytic Stroke (*Pakshaghata*) Management: Research Protocol for a Randomised Clinical Trial

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ABSTRACT

Introduction: Stroke is characterised by rapidly appearing signs and symptoms of focal (or global, in the case of coma) disruption of cerebral function lasting longer than 24 hours or resulting in death, with no detectable cause other than vascular origin. When an artery supplying the brain becomes blocked or bursts, some brain cells die due to lack of oxygen, resulting in a stroke. In Ayurveda, this can be correlated with *Pakshaghata*, meaning immobility of one side of the body (*Paksha* meaning the right or left half of the body and *Aghata*, or paralysis, indicating deterioration of *Karmendriya* (organ of action), *Gyanendriya* (sense organ) and *Manas* (mind)).

Need of the study: Sedentary lifestyles increase the risk of hypertension, dyslipidaemia, type 2 diabetes mellitus, etc., *Vashti* helps nourish, strengthen and stabilise the body's overall function, aiding stroke recovery. *Nasya karma* aims to remove clots and replenish blood supply to the injured brain site; it is used in *Urdhva jatrugata Roga* and helps strengthen muscles and nerves, increasing blood supply.

Aim: To assess the effectiveness of *Kusumbhadya Taila Matra Vasti* versus *Kusumbhadya Taila Nasya* as adjuvant therapy with standard care in treating thrombolytic stroke (*Pakshaghata*).

Materials and Methods: A randomised, single (assessor) blind, three-arm superiority clinical trial will be conducted at Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod, Wardha, Maharashtra, India from November 2024 to October 2025. Sixty patients will be divided into three groups: Group A (N=20)–standard care with physiotherapy for 11 days (control group); Group B (N=20)–*Kusumbhadya Taila* medicated enema+standard care with physiotherapy for 11 days; Group C (N=20)–*Kusumbhadya Taila* nasal administration+standard care with physiotherapy for 11 days (experimental group). The Dynamic Gait Index (DGI), Berg Balance Scale (BBS), Barthel Index and NIH Stroke Scale (NIHSS) will be assessed on days 3, 11 and 33. One-way Analysis of Variance (ANOVA) will be used to compare means; if significant, post-hoc tests (e.g., Tukey's HSD) will be applied. A p-value <0.05 will be considered statistically significant.

Keywords: Cerebral ischaemia, Ischaemic stroke, *Nasya karma*, *Taila matra vasti*, Thrombolytic therapy

INTRODUCTION

Stroke is the sudden onset of a localised neurological deficit caused by disrupted blood flow to the relevant brain region. A Transient Ischaemic Attack (TIA) is a localised neurological impairment lasting less than 24 hours [1].

Ayurveda describes illness as a derangement of one or more *doshas*; treatment aims to restore balance. The ancient Ayurvedic literature provides a detailed description of *pakshaghata*, also known as hemiparesis. *Vashti* nourishes and strengthens the body, aiding stroke recovery. *Nasya karma* removes clots and replenishes blood supply to the injured brain site; it's used in *Urdhva jatrugata Roga* and strengthens muscles and nerves, increasing blood supply [2]. The optimal oil for *Sneha Nasya* is *Vatahara Sneha*, enhancing *bala*. *Sneha* may have aided in restoring motor function by nourishing the *Gritakaram Majjaas Samanyo Vridhikaranam* [3]. *Basti* is *Ardh Chikitsa* in *Vata Vyadhi* [4]. *Shakha*, *Koshtha*, *Marma* and other ailments are primarily caused by *Vayu* [4]. *Basti* effectively eliminates *Dosha* or *Mala* [4].

A constructive analysis of the benefits of *Kusumbhadya* oil components is illustrated in [Table/Fig-1] [5-14].

Name of the drug	Properties of drugs which break the disease pathology
Kushumbha (<i>Carathmus Tinctorius</i>) [5]	Vata-pacifying, anti-inflammatory properties.
Khasa (<i>Chrysopogon zizanioides</i>) [6]	Strengthen and calm the nerves, reduce muscle stiffness and stimulate circulation.
Manjishta (<i>Rubia Cardifolia</i>) [7]	Kapha is increased and vata is decreased by <i>madhura</i> and <i>tikta rasa</i> . Anti-inflammatory properties.
Rakta Chandana (<i>Pterocarpus Santalinus</i>) [8]	Pacify excess heat associated with <i>Vata</i> imbalance and promote a sense of calmness and relaxation. Improve blood circulation, a natural analgesic.
Vateria indica (<i>Sarjarasa</i>) [9]	Anti-inflammatory properties, it may help mitigate secondary brain injury and promote recovery, exhibit antiplatelet activity.
Saussurea lappa (<i>Kushtha</i>) [10]	Neuroprotective effects: It exhibits antiplatelet effects, which can help prevent abnormal blood clotting and protect brain tissue from oxidative damage.
Tinospora cordifolia (<i>Guduchi</i>) [11]	Improves blood circulation and helps to regulate the immune response.
Cyperus rotundus (<i>Musta</i>) [12]	Cardiovascular benefits, including regulating blood pressure and heart function, have calming and stress-reducing properties and reduce neuroinflammation.

<i>Shatavari (Asparagus Racemosus)</i> [13]	Adaptogenic properties, stress-reducing effects and survivors experiencing anxiety or mood disturbances.
<i>Glycyrrhiza glabra</i> [14]	Anti-inflammatory properties protect neurons from oxidative damage.

[Table/Fig-1]: Role of Kusumbhadya oil in thrombotic stroke based on properties of each component [5-14].

REVIEW OF LITERATURE

The dried flowers of *Carthamus tinctorius* L., safflower, are red and blue. Safflower contains flavonoids, alkaloids and organic acids; its flavonoid content includes chalcone, dihydroflavone, flavonoids and flavonol. Safflower alleviates blood stasis, relieves pain, enhances blood flow and opens channels. It has therapeutic effects on blood stasis, preventing cardiovascular and cerebrovascular disorders. Safflower prevents ischaemic brain damage by promoting antistress activities, preventing platelet aggregation, reducing blood viscosity, inhibiting vascular smooth muscle growth, lowering blood pressure and exhibiting anti-inflammatory properties [5]. Traditionally, *C. tinctorius* flowers have been used for gynaecological, cardiovascular and cerebrovascular issues [5,15]. Linoleic acid, an unsaturated fatty acid in safflower seed oil, lowers blood cholesterol. Consumer preference for healthier oils with lower saturated fat reduces arteriosclerosis [16].

Yousefi M et al., evaluated safflower's effects on NIH Stroke Scale (NIHSS) scores in ischaemic stroke patients. Group A received nasal safflower oil drops and oral safflower extract syrup; Group B received standard anti-ischaemic treatment [17]. Group A showed a statistically significant mean difference in NIHSS scores from baseline to 15 days post-treatment compared to Group B (p-value <0.001). After controlling for confounding variables, neurological state differences were not significant, but neurological symptom score variations were statistically significant. This suggests that safflower as an adjunct therapy may enhance ischaemic cerebrovascular event management [17].

Wang Y et al., investigated safflower's mechanisms in treating cerebral infarction via the nasal route using a Middle Cerebral Artery Occlusion (MCAO) model. Safflower effectively treats cerebral infarction by regulating the TNF- α /MAPK pathway through CASP3. Its therapeutic effects improve central nervous system blood circulation, mitigate inflammatory responses, inhibit apoptosis and protect neuronal cells [15].

This study evaluates the efficacy of two *Carthamus tinctorius* (*Kusumbhadya Taila*) administration routes (rectal and nasal) as adjuvant therapy with standard care and physiotherapy in thrombotic stroke (*Pakshaghata*) rehabilitation.

Primary Objectives:

- To study the efficacy of *Carthamus tinctorius* (*Kusumbhadya Taila*) administered rectally (medicated enema) as adjuvant therapy.
- To study the efficacy of *Carthamus tinctorius* (*Kusumbhadya Taila*) administered nasally as adjuvant therapy.

Secondary Objectives:

- To compare the efficacy of *Carthamus tinctorius* administered rectally (medicated enema) versus nasally.

Null hypothesis: There will be no significant difference in the efficacy of *Kusumbhadya Taila* administered nasally and rectally in thrombotic stroke (*Pakshaghata*) rehabilitation as adjuvant therapy.

Alternative hypothesis: There will be a significant difference in the efficacy of *Kusumbhadya Taila* (*Carthamus tinctorius* and group of drugs) administered rectally and nasally in thrombotic stroke (*Pakshaghata*) rehabilitation.

MATERIALS AND METHODS

A randomised, single (assessor) blind, three-arm superiority comparative clinical trial will be conducted at Mahatma Gandhi

Ayurved College Hospital and Research Centre, Salod, Wardha, Maharashtra, India from November 2024 to October 2025. Ethical approval (MGACHRC/IEC/Sep-2023/720) has been obtained. The trial is registered on the CTRI website (CTRI/2023/10/058608).

Inclusion criteria:

- Patients with recently diagnosed (15 days to 6 months) thrombotic stroke via brain Magnetic Resonance Imaging (MRI).
- Patients aged 21-70 years, of either gender, providing written informed consent and adhering to instructions.
- Patients suitable for medicated enema and nasal administration.
- Patients with controlled hypertension (systolic BP ≤ 140 mmHg, diastolic BP ≤ 90 mmHg) and controlled diabetes (FBS < 130 mg/dL, PPBS < 180 mg/dL) [18].

Exclusion criteria:

- Patients with cardiac diseases (Acute myocardial infarction, angina, etc.).
- Patients with diabetic neuropathy or retinopathy.
- Pregnant or lactating women.
- Patients with acute complications (cirrhosis, pancreatitis, hypoglycaemic shock).

Sample size:

Sample size calculation using the formula:

$$N = \frac{[(Z_{\alpha/2} + Z_{\beta})^2 \{P_1(1-P_1) + P_2(1-P_2)\}]}{(P_2 - P_1)^2}$$

$Z_{\alpha/2} = 1.96$ (95% CI)

$Z_{\beta} = 0.84$ (80% power)

N=Minimum samples required per group

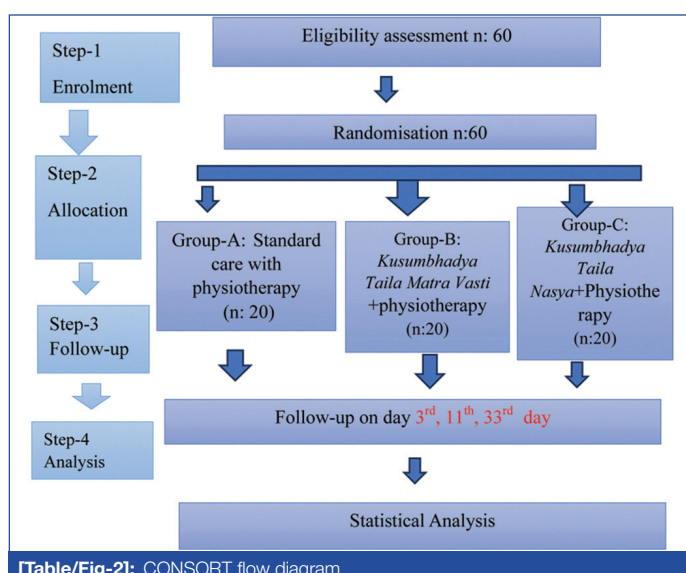
Primary variable=% improvement in NIHSS

NIHSS in pentoxifylline (control group)=32%

Clinically significant improvement margin=45% over the control group [19].

A total of 60 patients will be included, divided into three groups. Group A (N=20)–standard care with physiotherapy for 11 days (control group); Group B (N=20)–*Kusumbhadya* oil (*Carthamus tinctorius* and group of drugs) medicated enema+standard care with physiotherapy for 11 days; Group C (N=20)–*Kusumbhadya* oil (*Carthamus tinctorius* and group of drugs) nasal administration+standard care with physiotherapy for 11 days [Table/Fig-2,3].

Raw materials will be sourced from a certified retailer. The Dravya Guna department of Mahatma Gandhi Ayurved College and Hospital, Wardha, will standardise the drug. *Kusumbhadya Taila* will be prepared in Dattatreya Ayurved Rasashala, Salod (H),



[Table/Fig-2]: CONSORT flow diagram.

Group	Sample size	Intervention	Dose and frequency	Procedure time	Duration	Follow-up
A	20	Standard care with physiotherapy	Aspirin 75 mg OD Pentoxifylline 400 mg TDS	30-60 min	Eight days	3 rd , 11 th , 33 rd day
B	20	Deepana (Enhancement of digestive fire), Pachana (Digestion of Toxins)+Kusumbhadya tail Medicated Enema (Matra Vasti)+standard care with physiotherapy	Once a day (in the morning) 60 mL after lunch	30-60 min	3 days for digestion of toxins and enhancement of digestive fire+8 days for medicated oil enema Total-11 days	3 rd , 11 th , 33 rd day
C	20	Deepana (Enhancement of digestive fire), Pachana (Digestion of Toxins)+Kusumbhadya Tail Nasal administration+standard care with physiotherapy	8-8 drops in each nostril once a day before lunch	30-60 min	3 days for digestion of toxins and enhancement of digestive fire+8 days for medicated oil nasal administration Total-11 days	3 rd , 11 th , 33 rd day

[Table/Fig-3]: Showing grouping and posology along with treatment period and follow-up period.

Wardha, according to the standard operating procedure in *Gada Nigraha* [20].

Carthamus tinctorius (Kusumbha) is used instead of Kesar (Abhav Pratinidhi Dravya) to reduce costs. The drug's components, quantities and properties are shown in [Table/Fig-4,5] [21].

Drug preparation: A fine paste of all raw drugs (1 kg each) will be mixed with sesame oil (1 part) and water (4 parts). According to *Taila Paka Vidhi*, it will be boiled at 60-120°C until reduced to 1/4th. The oil will be filtered and stored.

S. No.	Ingredients	Latin name	Part used	Quantity
1.	Kusumbha	<i>Carathmus Tinctorius</i>	Flower	2 part
2.	Khasa	<i>Chrysopogon Zizaniodes</i>	Roots	1 part
3.	Manjishtha	<i>Rubia Cardifolia</i>	Roots	1 part
4.	Rakta Chandan	<i>Pterocarpus Santalinus</i>	Heart Wood	1 part
5.	Mom (Wax)	-	-	1 part
6.	Sarjarasa	<i>Vateria Indica</i>	Exudate	1 part
7.	Atank (Kushta)	<i>Saussurea Lappa</i>	Roots	1 part
8.	Guduchi	<i>Tinospora Cardifolia</i>	Stems	1 part
9.	Saindhav Lavan	Rock Salt	-	1 part
10.	Motha	<i>Cyperus Rotundus</i>	Roots	1 part
11.	Murva	<i>Marsdenia Tenacissima</i>	Roots	1 part
12.	Shatavari	<i>Asparagus Racemosus</i>	Roots	1 part
13.	Laksha	<i>Laccifer Lacca</i>	-	1 part
14.	Yasthimadhu	<i>Glycyrrhiza Glabra</i>	Roots	1 part
15.	Til Taila	<i>Sessamum Indicum</i>	-	1 part

[Table/Fig-4]: Details of drug preparation.

Name [21]	Rasa	Guna	Veerya	Vipaka	Karma	Doshgati
Kusumbha	Katu, Kashaya	Guru, Ruksha	Shita	Katu	Balya, Mutrala, Swedajanan	Kaphapittahara
Khasa	Tikta, Madhura	Ruksha, Laghu	Shita	Katu	Pachan, Stambhan, Dahahara, Jwarahara	Vatapittahara
Manjishtha	Madhura, Tikta	Guru, Ruksha	Ushna	Katu	Grahi, Chakshuya, Kandughna, kushthagna	Kaphapittahara
Rakta Chandan	Tikta, Madhura	Guru, Ruksha	Shita	Katu	Jwarahara, Dahaprashamanhara, Raktapittahara, Shothahara	Kaphapittahara
Mom (Wax)	-	-	-	-	-	-
Sarjarasa	Kashaya, Tikta	Snigdha	Shita	Katu	Grahi, Kusthagna, Krimighana	Vatapittahara
Atank (Kushta)	Tikta, Katu, Madhura	Laghu, Ruksha, Tikshna	Ushna	Katu	Hikkanigrahan, Kandughna, Medohara	Vatakaphahara
Guduchi	Kashaya, Tikta	Laghu	Ushna	Madhur	Rasayni, Sangrahini, Balya	Tridoshahara
Saindhav Lavan	Lavana	Snigdha, Ushna, Teekshna	Anushnasheeta	Madhur	Rochana, Deepana, Vrishya, Avidahi	Kaphavatashamak
Motha	Tikta, Katu, Kashaya	Laghu, Ruksha	Sheeta	Katu	Deepan, Grahi, Kasahara, Jwarahara	Kaphapittahara
Murva	Tikta, Kashaya	Guru, Ruksha	Ushna	Katu	Jwaraghna, Kusthagna, Chardighana	Kaphavatahara
Shatavari	Madhua, Tikta	Guru, Snigdha	Shita	Madhur	Balya, Rasayana, Sukrala Vayasthapana	Vatapittahara
Laksha	Kashaya, Tikta	Laghu, Snigdha	Shita	Katu	Varnya, Hikkanigrahana, Swasahara	Kaphapittahara
Yasthimadhu	Madhua	Guru, Snigdha	Sheeta	Madhur	Varnya, Kanthya, Snehopag	Vatapittahara
Til Taila	Madhur, Kashaya, Tikta	Guru, Snigdha	Ushna	Madhur	Twachya, Keshya, Shukrala, Balya, Vednasthapana	Vatahara

[Table/Fig-5]: Showing ayurvedic properties of drugs used [21].

Nasya Karma (Nasal Oil Administration):

Preprocedure (Poorvakarma): A well-lit, dust-free area is required. Gather materials (table, chair, steam, medicine, towel, cotton, bowl, oil).

Fitness of the patient (Aturasiddhata): The patient lies with their head tilted back, a towel under their neck. Facial and head massage (*Mukha* and *Shiroabhyanga*) is performed, followed by gentle steaming.

Principal protocol (Pradhanakarma): The patient's head is lowered, eyes covered. Eight oil drops are administered gradually, with repeated light steaming of hands, feet, forehead and cheeks. The patient spits out oil entering the throat. Swallowing medication that enters the digestive tract is not advised.

Postprocedure (Paschatakarma): After spitting, the mouth and throat are rinsed with warm water. Medicated smoke (*Dhoompana*) is advised. A 5–10-minute rest follows.

Medicated Oil Enema:

Preprocedure (Poorva karma): Evacuation of the bowel and bladder is a must for the patients before the procedure. Mix 60 mL of *Kusumbhadya Taila* with 2 grams of rock salt and warm it to a lukewarm temperature using the double heating method (placing the container in hot water). Patients are advised to consume a proper meal before the procedure.

Main procedure (Pradhana karma): The patient lies in the left lateral position (*Vama Parshwa*). The anal canal was filled with one-fourth of the rubber catheter after the anal ridge and tip were lubricated. Over eight days, 60 millilitres of lukewarm therapeutic oil will be gradually administered once a day using a syringe. To

avoid any blockages, the syringe will be held high. Afterwards, the catheter will be taken out.

Postprocedure (Paschat karma): Patients will be encouraged to lie in a supine position and take a moment to relax. To allow the medicated enema to disperse throughout the body, the patient will remain comfortable for the count-up to 100 (100 Vak). Gentle massage to the patient's back and buttocks will be given with both palms rubbed together [22].

Retention time: Nine hours (3 *Prahara*).

Diet and aftercare: A suitable diet (*Yusha, Mamsa Rasa*, etc.) and lukewarm water are provided.

Assessment Criteria

Dynamic gait index: DGI is a clinical tool used to assess an individual's ability to maintain balance while walking under various dynamic conditions. It evaluates gait and balance by testing eight different tasks, each scored on a scale from 0 to 3, with 3 indicating normal performance and 0 indicating severe impairment. The total score ranges from 0 to 24, with higher scores indicating better balance and gait [23].

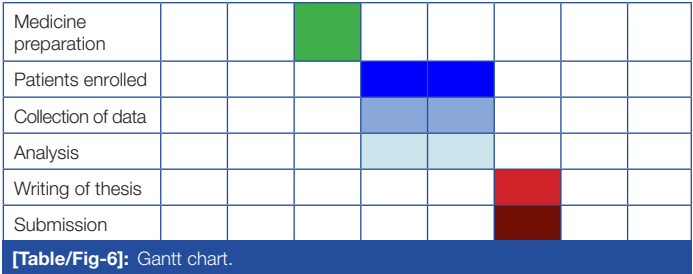
Berg balance scale: BBS is a 14-item measure that uses direct performance observation to objectively evaluate older persons living in the community for their balance and fall risk. The items are between 0 and 4, where 0 denotes an inability to finish the job, and 4 denotes independent item completion. A total score of 0-20 indicates impaired balance, 21-40 indicates acceptable balance and 41 -56 indicates good balance. The BBS assesses the balance's dynamic and static components [24].

Barthel index: BI is a widely used tool to assess an individual's ability to perform ADLs. The index measures the level of assistance a person requires in various ADLs, with higher scores indicating greater independence. Each task will be scored on a scale from 0 to 10, with 0 indicating complete dependence and 10 indicating complete autonomy. The total score ranges from 0 to 100, with higher scores indicating better functional independence [25].

National Institutes of Health Stroke Scale: NIHSS measures stroke severity is a 15-item scale. The following domains are included in the NIHSS: language, speech, neglect, eye movements, facial motions, arm and leg muscle strength, sensation, coordination, and state of consciousness. On an ordinal scale with a range of 0 to 2, 0 to 3, or 0 to 4, each disability will be assessed. The sum of the item scores results in a total score from 0 to 42; the greater the number, the more serious the stroke [26]. Assessments are performed on days 3, 11 and 33.

STATISTICAL ANALYSIS

The statistical analysis will be conducted using Statistical Package for the Social Sciences (SPSS) version 7.0 software. One-way ANOVA will compare the means of the three groups. Post-hoc tests (e.g., Tukey's HSD) will be applied if ANOVA indicates a significant difference. A p-value <0.05 will be considered statistically significant. Following table presents the Gantt chart [Table/Fig-6].



[Table/Fig-6]: Gantt chart.

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Guidelines: SPIRIT Guidelines are being followed.

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Title	Evaluation of Comparative Efficacy of two different routes of administration of <i>Kusumbhadya Taila</i> (Medicated Enema and Nasal Administration) as an adjuvant therapy with standard care with physiotherapy in the rehabilitation of thrombolytic stroke (<i>Pakshaghata</i>).							
Steps	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
IEC authorisation								
Overview of the literature								

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