

# Ayurvedic treatment in the rehabilitation of ischemic stroke

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<b>Registration date</b> 16/03/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/03/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

After a stroke, two-thirds of the survivors have a functional disability that impairs their activities of daily living. Effective stroke rehabilitation remains an essential part of stroke care and leads to improvement in physical disability, better social life, employment, and quality of life.

Conventional physiotherapy, a mainstream for stroke rehabilitation, is proven to be effective by several randomized controlled trials and systematic reviews. Because of its convenience and practicability, physiotherapy is frequently used to improve the functional recovery of stroke patients in the acute phase.

Ayurveda is a distinctive system of treatment that has been practised in India for stroke rehabilitation. There are no randomised controlled data available on its safety and effectiveness. The study aims to determine the safety and effectiveness of Ayurvedic treatment in the rehabilitation of stroke patients and to compare the effectiveness of Ayurvedic treatment over conventional physiotherapy in the rehabilitation of stroke patients.

### Who can participate?

Patients aged over 18 years and who had their first episode of ischemic stroke defined on CT scan or MRI brain and presentation between 1 month to 3 months of stroke onset

### What does the study involve?

Participants are randomly allocated to the intervention group or the control group.

Participants allocated to the intervention group will receive Ayurveda treatment for 29 days as per the treatment protocol. The treatment includes procedures like Dhanyamla Dhara, Ksheera Dhooma, Patrapodala Swedam (induced sweating), Virechana, Dhanya Pinda Swedam (induced sweating), and Madhu Tailika Vasti (medicated enema).

All patients in the control group will receive conventional physiotherapy. Physiotherapy intervention will be given 5 days per week for 5 weeks (25 days). The duration of therapy will be 1 hour per day. The intervention is delivered by the study physiotherapist either at home or at the outpatient unit. The physiotherapy treatment procedures include passive and/or active range of motion exercises, weight-bearing, and supportive reaction, reaching activities, grasping, holding, and release, upper extremity activities of daily living (ADLs); lower extremity ADLs, gait training, trunk exercises, and facilitatory exercises for upper limb and lower limbs.

What are the possible benefits and risks of participating?

There are no risks associated with participating in this study. The Ayurveda treatment involves only the routine ayurvedic procedures that are performed to improve the strength and vitality of individuals. Physiotherapy rehabilitation involves the widely accepted rehabilitation techniques performed on stroke patients. Patients might experience minor discomforts like mild pain with physiotherapy, mild pain, slight fatigue, and occasional stomach irritation with Ayurveda treatment.

The rehabilitation modalities (Ayurveda/physiotherapy) are expected to be beneficial in improving the recovery of patients from stroke. These rehabilitation strategies might help in improving the functional ability, ability to perform activities of daily living, and quality of life.

Where is the study run from?

1. Sree Chitra Tirunal Institute of Medical Sciences and Technology (India)
2. Christian Medical College & Hospital, Ludhiana, Punjab (India)
3. Amrita Institute of Medical Science, Kochi (India)
4. Jawaharlal Institute of Postgraduate Medical Education & Research, Pondicherry (India)

When is the study starting and how long is it expected to run for?

March 2018 to November 2022

Who is funding the study?

Indian Council of Medical Research (India)

Who is the main contact?

Dr P N Sylaja, [sylajapn@sctimst.ac.in](mailto:sylajapn@sctimst.ac.in)

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof P N Sylaja

### ORCID ID

<https://orcid.org/0000-0003-4896-8275>

### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

RESTORE Protocol Version 1.2 dated 04 March 2020, CTRI/2018/04/013379

## Study information

**Scientific Title**

Ayurvedic treatment in the rehabilitation of ischemic stroke patients in India: a randomized controlled trial

**Acronym**

RESTORE

**Study objectives**

The study hypothesizes that Ayurvedic rehabilitative treatment is superior to similar duration conventional physiotherapy in improving the sensorimotor recovery of patients with ischemic stroke at 90 days after enrolment.

Before the study initiation, the study was registered in the Clinical Trials Registry - India (CTRI) with registration number CTRI/2018/04/013379 dated 19/04/2018.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 02/07/2018, Institutional Ethics Committee, Sree Chitra Tirunal Institute for Medical Sciences and Technology (Trivandrum, Kerala - 695011, India; +91 (0)471-2524689; iec.mem.sec@sctimst.ac.in), ref: SCT/IEC/1183/JUNE 2018

**Study design**

Single-blinded randomized controlled blinded assessment (PROBE design) trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Rehabilitation in ischemic stroke

**Interventions**

The eligible patients will be randomized using a central, web-based, block randomization process to assign the study arm. The researcher randomizing the subjects at the participating centres (four centres) will receive the allocation status by entering the patient details in the randomization web portal (<https://easyresearch.instructnetwork.in/EasyResearch/AribaWeb/>). Eligible patients will be block randomized and stratified by the study centre in a 1:1 ratio to have a balance between the number of subjects in the intervention and the control arm.

The patients allocated to the intervention arm will receive Ayurveda Rehabilitation Treatment (ART) for 29 days as per the treatment protocol. The treatment includes procedures like Dhanyamla Dhara, Ksheera Dhooma, Patrapodala Swedam (induced sweating), Virechana, Dhanya Pinda Swedam (induced sweating), and Madhu Tailika Vasti (medicated enema). The intervention is provided as an in-patient treatment at the ayurvedic centres and all intervention procedures will be performed under the direct supervision of an ayurvedic physician.

All patients in the control group will receive conventional physiotherapy. Physiotherapy intervention will be given 5 days per week for 5 weeks (25 days). The duration of therapy will be 1 hour per day. The intervention is delivered by the study physiotherapist either at home or at the outpatient unit. The physiotherapy treatment procedures include passive and/or active range of motion exercises, weight-bearing, and supportive reaction, reaching activities, grasping, holding, and release, upper extremity activities of daily living (ADLs); lower extremity ADLs, gait training, trunk exercises, and facilitatory exercises for upper limb and lower limbs.

The patients will be followed for a 1-month and 3-month period to assess sensorimotor function using efficacy outcome scales.

### **Intervention Type**

Other

### **Primary outcome(s)**

Sensorimotor recovery assessed using the Fugl Meyer Assessment – Upper Extremity (FMA - UE) scale at the time of recruitment (baseline), at 1 month, and 3 months from the baseline

### **Key secondary outcome(s)**

Measured at the time of recruitment (baseline), at 1 month, and 3 months from the baseline:

1. Functional disability assessed using the modified Rankin scale (mRS)
2. Postural balance assessed using the Berg Balance Scale (BBS)
3. Quality of life assessed using Short form 36 (SF 36)
4. Activities of daily living assessed using the Barthel index (BI)

### **Completion date**

30/11/2022

## **Eligibility**

### **Key inclusion criteria**

1. First episode of ischemic stroke with a corresponding acute infarct observed on CT scan or MRI brain
2. Presentation between 1 month to 3 months of stroke symptom onset
3. Age group between 18-70 years
4. Modified Rankin Scale scores of 3 and 4 at the time of enrollment
5. Pre-stroke modified Rankin scale (mRS) less than or equal to 2

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

70 years

**Sex**

All

**Total final enrolment**

140

**Key exclusion criteria**

1. Bilateral symptomatic strokes
2. Intracerebral hemorrhage
3. Significant joint deformity preventing effective rehabilitation measures
4. Unstable cardiopulmonary status and other diseases which are likely to hamper effective rehabilitation (uncontrolled diabetes with HbA1c >8% or fasting blood glucose >130 mg/dl and postprandial blood glucose >180 mg/dl at the time of recruitment; history of hemorrhoids/rectal prolapse/anal fissure/anal fistula; allergic/infectious/ noninfectious skin disorders)
5. Current use of any other complementary and alternative therapy

**Date of first enrolment**

22/05/2019

**Date of final enrolment**

19/07/2022

**Locations****Countries of recruitment**

India

**Study participating centre**

**Sree Chitra Tirunal Institute for Medical Sciences and Technology**

Medical College Campus

Thiruvananthapuram

India

695011

**Study participating centre**

**Amrita Institute of Medical Sciences**

Ponekkara, AIMS. P.O

Kochi  
India  
682041

**Study participating centre**

**Jawaharlal Institute of Postgraduate Medical Education and Research**  
JIPMER Campus, Dhanvantari Nagar  
Puducherry  
India  
605006

**Study participating centre**

**Christian Medical College and Hospital**  
Brown Road, CMC Campus  
Ludhiana  
India  
141008

## Sponsor information

**Organisation**

Indian Council of Medical Research

**ROR**

<https://ror.org/0492wrx28>

## Funder(s)

**Funder type**

Government

**Funder Name**

Indian Council of Medical Research

**Alternative Name(s)**

Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, . . . ., ICMR, ICMRDELHI, ...

**Funding Body Type**

Government organisation

### Funding Body Subtype

National government

### Location

India

## Results and Publications

### Individual participant data (IPD) sharing plan

The dataset generated during and/ or analyzed during the current study will be available upon request from Dr P N Sylaja (sylajapn@sctimst.ac.in).

The type of data that will be shared: All the collected data

Dates of availability: until 5 years after the end of the trial.

Whether consent from participants was required and obtained: consent was required and was obtained.

Comments on data anonymization: the names of the participants were anonymised.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes