ISRCTN68137638 https://doi.org/10.1186/ISRCTN68137638

Ayurvedic treatment in the rehabilitation of ischemic stroke

Submission date	Recruitment status	[ ] Prospectively registered
09/02/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/03/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/03/2023	Circulatory System	[ ] 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 faciliatory 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

Study website
https://instructnetwork.in

Contact information

Type(s)
Principal Investigator

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Prof P N Sylaja

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

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 faciliatory 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 measure
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

Secondary outcome measures
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)

Overall study start date
28/03/2018

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
140

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

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Sponsor type
Government

Website
http://www.icmr.nic.in/

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

Publication and dissemination plan
The researchers have submitted the protocol and statistical analysis plan paper to a medium-impact peer-reviewed journal and intend to publish the main results paper within 3 months of completion of the study in a peer-reviewed high-impact journal.

Intention to publish date

30/06/2023

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