Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of Anti-inflammatory Effects of strowell capsules on Plasma Inflammatory Factors in Ischemic Stroke Patients: A Randomized, Double-blind Placebo-controlled Trial

Protocol summary

Study aim
Investigation of anti-inflammatory effect of strowell capsules on inflammatory factors in ischemic stroke patients

Design
Two arm parallel group randomized double-blind placebo-controlled trial

Settings and conduct
The trial is performed in Imam Hossein and Imam Khomeini Hospitals based on double-blind block randomization. All the people involved in the caregiving and treatment of the patients including companions, physicians, nurses and investigators are unbeknownst of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The inclusion age should be in 40-80 years range; National Institute of Health Stroke Scale (NIHSS) range is 4-20; and that of Body mass index (BMI) is 20-25. Focal neurological signs are confirmed by the Magnetic Resonance Imaging (MRI). Exclusion criteria: hemorrhagic stroke; history of Nonsteroidal Anti-inflammatory Drugs(NSAID) allergic response; history of gastrointestinal bleeding; kidney and liver failure; rheumatic and autoimmune diseases, myocardial infarction within previous 48 hours; previous stroke; pregnancy or lactation; malignancies; various other inflammatory diseases during the trial and those patients who have received tissue plasminogen activator (tPA).

Intervention groups
strowell capsules receiving group Placebo group

Main outcome variables
"Stroke intensity" "Blood Inflammatory markers"

General information

Reason for update
Due to publishing the results of the study under the brand name Strowell, title has been modified accordingly.

Acronym

IRCT registration information
IRCT registration number: **IRCT20170315033086N5**
Registration date: **2019-05-05, 1398/02/15**
Registration timing: **retrospective**

Last update: **2021-06-13, 1400/03/23**
Update count: **1**

Registration date
2019-05-05, 1398/02/15

Registrant information

Name
Saeed Karima

Name of organization / entity
Shahid Beheshti University of Medical Sciences (SBMU)

Country
Iran (Islamic Republic of)

Phone
+98 21 9666 1028

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karima@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-01, 1396/02/11

Expected recruitment end date
2018-08-02, 1397/05/11

Actual recruitment start date
2017-06-25, 1396/04/04

Actual recruitment end date
2018-12-01, 1397/09/10

Trial completion date

2019-02-20, 1397/12/01

Scientific title

Investigation of Anti-inflammatory Effects of strowell capsules on Plasma Inflammatory Factors in Ischemic Stroke Patients: A Randomized, Double-blind Placebo-controlled Trial

Public title

Circulatory Cytokine Profiles of Ischemic Stroke Patients after Treatment with strowell capsules

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis, based on neurological diagnostic signs and confirmed by Magnetic Resonance Imaging (MRI) National Institutes of Health Stroke Scale (NIHSS) should be in 4 - 20 range at the time of admission. Body mass index (BMI) should be in 20-25 range No inflammatory diseases

Exclusion criteria:

Hemorrhagic stroke transient ischemic attack (TIA) History of gastrointestinal bleeding History of sensitivity to NSIADs Previous stroke Myocardial infarction within the previous 48 hours Kidney and liver failure Immunosuppressive medications Stroke patients who have received tissue plasminogen activator (tPA). Rheumatoid and autoimmune diseases Malignancies Pregnancy or lactation

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is designed based on four-sized block randomization procedure. A non-ordered computer sequence list including the patient-assigned code and the order of recruitment is generated by an epidemiologist. Given the block size of 4, there are 6 possible ways to equally assign participants to each treatment group. Therefore recruitment of participants to each treatment category is randomized and unpredictable. Following this randomization, an equal number of participants is randomly assigned to each treatment group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient allocation and sequencing are done blindly. All the members of the staff who are involved in performing the enrollment, physicians, nurses and the investigation team as well as patients and their guardians, are masked. The research group is uninformed of drug and/or placebo prescription and its dosage. Codes will be written on the sealed envelopes and the medication bottles. Following patient assessment by the doctor, according to the admission sequence, the envelopes with the same number will be opened. Subsequently, the patients are going to be handed a bottle that could be the drug or placebo based on the assigned code. Therefore, the patient is unbeknownst whether the intervention is strowell capsules or the placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences, School of Medicine

Street address

Ground floor, medical faculty, Koodakyar Alley, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

IR.SBMU.MSP.REC.1395.409

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description
Stroke intensity
Timepoint
At the commencement of the investigation and after taking the strowell capsules
Method of measurement
NIH Stroke Scale questionnaire for quantifying stroke severity (11 items are included, level of consciousness, horizontal eye movement, visual field test, facial palsy, motor arm and motor leg, limb ataxia, sensory, language, speech, extinction and inattention)

2

Description
Pro- and anti-inflammatory plasma markers
Timepoint
At the investigation commencement and after the intervention
Method of measurement
ELISA assay kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: strowell capsules receiving group, 1 month, 3 times/day, Oral Administration (800 mg)
Category
Treatment - Drugs

2

Description
Control group: Placebo group,1 month, 3 times/day, Oral (800 mg)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Behnam Safarpour Lima
Street address
Shahid Madani St., Tehran, Iran
City
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1617948615
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Behnam Safarpour Lima
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
collected de-identified IPD, IPD collected for the primary outcome measure only
When the data will become available and for how long
De-identified data will be available starting from April, 2021
To whom data/document is available
Academics employed at various research/university institutions and the industry.
Under which criteria data/document could be used
No specific condition are specified.
From where data/document is obtainable
Behnam Safarpour Lima, Shahid Madani St., Tehran, Iran, Tel: +982173433000 Mob. 091229811576
What processes are involved for a request to access data/document
1- The applicant would be asked to provide a written formal request letter, containing the importance of the data and the project processes. 2- Following the receipt of request letter, the data would be provided in no more than two weeks.
Comments