Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Explanation of cerebrovascular attack (CVA) based on Iranian traditional medicine (ITM) and evaluation of clinical trial an ITM – based protocol and modern medical- based protocol on clinical improvement of CVA

Protocol summary

Summary

The main purpose of the project was to investigate the role of stroke in persian medicine and the effect of therapy on the course of treatment . In fact, the present qualitative research was based on Clinical Trial. First, the materials are collected, and then the basics of stroke were discussed. Subsequently, in the phase of clinical trial, the patients were admitted to the neurology department of Ghaem Hospital, Mashhad, Iran, based on their clinical examination and CT brain scan diagnosis of CVA. A comprehensive questionnaire was given to each patient on admission, and their consent was obtained. All the moral principles were established to the patients. The patients participating in the project were matched at baseline. In addition, they were randomly assigned to intervention and control groups. The control group was given the modern medicine package, and the intervention group received the traditional medicine package. The current study was a randomized, double-blind treatment. Throughout the hospitalization period, the exprts visited the patients every day and the whole treatment was under their careful supervision.

General information

Acronym

CVA:cerebro vascular attack

IRCT registration information

IRCT registration number: **IRCT2015122025622N1**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

Elahe Delshad

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Mashhad University of Medical Sciences

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Explanation of cerebrovascular attack (CVA) based on Iranian traditional medicine (ITM) and evaluation of clinical trial an ITM – based protocol and modern medical- based protocol on clinical improvement of CVA

Public title

evaluation of an ITM – based protocol on clinical improvement of CVA

Purpose

Treatment

Inclusion/Exclusion criteria
In our study, the inclusion criteria encompassed patients whom were discovered to have focal neurological symptoms after their brain imaging, being diagnosed with ischemic CVA. On the other hand, the exclusion criteria were as follows: 1. patients with focal neurological findings ith regard to the candidate symptoms of venous rTPA; 2. patients with symptoms in less than 24 hours of a TIA with normal imaging raises; 3. patients on admission with NIHSS Score and analytically based on a bad prognosis. 4. patients with chronic systemic diseases such as uremia, chronic liver disease, and high blood pressure a potential impact would be on our protocol and our intervention would accelerate HIV disease; 6. patients with possible teratogenic effects of safflower pregnancy; 7. patients having any evidence of brain hemorrhage; 8. patients receiving anticoagulant (heparin or warfarin); 9. incidence of venous infarcts in venous sinus thrombosis; 10. patients reluctant to continue double-blind treatment. During hospitalization, the patients were visited on a daily basis by experts who closely supervised the treatment.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this randomized study is done based on random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Ghoreshi department, Avenue Daneshgah, Mashhad

City
Mashhad

Postal code

Approval date
2015-12-13, 1394/09/22

Ethics committee reference number
IR.MUMS.REC.1394.555

Health conditions studied

1

Description of health condition studied
Ischemic cerebro vascular attack

ICD-10 code
G46.4*

ICD-10 code description
cerebro vascular syndrom

Primary outcomes

1

Description
Score of disability based on Questionnaire NIHSS

Timepoint
Baseline and one month after presentation

Method of measurement
Clinical examination by an expert on the NIHSS score

Secondary outcomes

1

Description
Biochemical markers

Timepoint
Baseline and one month after the initial visit

Method of measurement
blood test

Intervention groups

1

Description
The intervention group, in addition to the current anti-ischemic drugs, ITM, based protocol will be prescribed. - Traditional Therapy package includes an oral syrup safflower extract and safflower oil is a nasal drop. Venice is a barley soup (including barley, celery, prune, tamarind, candy and a little salt and turmeric) is included in the patient's diet - dose nasal drops 3 drops in each nostril every 4 hours Mybashd.bh a month - barley soup In the first two weeks the patient will be referred to the main course. A 100 ml bottle of safflower syrup prepared with a concentration of 25% by volume weight twice daily to patients is recommended every 5 ml of the syrup mill. For a month

Category
Treatment - Drugs

2

Description
Routin anti-ischemic drugs plus a placebo given to the control group. Current treatments include aspirin 325 mg daily, and 20 mg Trvstatyn and, if not above the patient's creatinine is 30 cc daily Piracetam. Inert placebo form of the drug is similar to the intervention group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Guaem hospital of Mashhad University of Medical Sciences

Full name of responsible person
Delshad Elahe

Street address
Guaem hospital, Ahmadabad Avenue

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Mashhad University of Medical Sciences

Full name of responsible person
Dr. Saeed Eslami

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Ghoreshi departman, Daneshgah Avenue

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Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research,Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Delshad Elahe

Position
Phd student of Traditional Medicin

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty