

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Dorema ammoniacum and acupuncture on the clinical improvement of patients with cerebral stroke

Protocol summary

Study aim

The effect of Dorema ammoniacum and acupuncture on the clinical improvement of patients with cerebral stroke

Design

In this study, 57 patients with ischemic stroke and inclusion criteria of the study who are referred to Ghaem Hospital in Mashhad are selected. Patients are randomly assigned into three categories by using Random number table.

Settings and conduct

Patients with ischemic stroke referred to Mashhad Ghaem Hospital are examined by neurologist and if they have inclusion criteria, they will enter the study after obtaining written informed consent.

Participants/Inclusion and exclusion criteria

Major inclusion criteria of the study is ischemic stroke in the past 30 days; major condition for not entering the study is the presence of hemorrhagic stroke.

Intervention groups

All groups receive standard treatment and physiotherapy. People in the first group receive one gram of Dorema ammoniacum gum and patients in group 2 receive acupuncture. The third group is control group and receives only standard treatment and physiotherapy.

Main outcome variables

Disability due to cerebral stroke (modified NIHSS standard questionnaire and modified Rankin scale standard questionnaire) : Aspartate aminotransferase : Low density lipoprotein : High density lipoprotein : Alanine aminotransferase : Blood urea nitrogen : Glycosylated hemoglobin : Triglyceride : Complete Blood Count : Fasting blood sugar : Creatinine : Partial thromboplastin time : Prothrombin Time : International Normalized Ratio (INR) : Cholesterol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170227032797N2**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9279

Email address

mehrpourm911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Dorema ammoniacum and acupuncture on the clinical improvement of patients with cerebral stroke

Public title

Effect of Dorema ammoniacum and acupuncture in treatment of cerebral stroke

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with focal neurological findings that have been clinically and with brain imaging have been diagnosed with ischemic stroke Ischemia is in the superior branch of middle cerebral artery Stroke attack in less than thirty days Age between 50 and 75 years First stroke attack Modified NIHSS between 4 and 20 Patient with consciousness and stable disease condition
Exclusion criteria:
 Cerebral stroke of hemorrhagic type Patients suffering from systemic chronic diseases such as: uncontrolled diabetes, severe liver, cardiac, renal or pulmonary disorders or cancer Patients taking coagulants (heparin or warfarin) Patients with BMI above 35 Patients with history of acupuncture in less than a month Patients with a history of allergy to Dorema Ammoniacum Patient suffering from severe musculoskeletal or neurologic diseases before ischemic stroke Patients diagnosed with tumor or skin infections

Age
From **50 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **57**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned into three categories: A, B, and C using Random number table

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

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

Sciences, Quraishi Building, Daneshgah St.
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 ۳۴۵ - ۹۱۳۷۵
Approval date
 2016-12-07, 1395/09/17
Ethics committee reference number
 IR.MUMS.REC.1395.518

Health conditions studied

1

Description of health condition studied
 Cerebral infarction
ICD-10 code
 I63
ICD-10 code description
 Cerebral infarction

Primary outcomes

1

Description
 Disability due to cerebral stroke
Timepoint
 Before the intervention, After the end of the intervention
Method of measurement
 MNIHSS and mRankin scales

Secondary outcomes

1

Description
 Aspartate aminotransferase
Timepoint
 before intervention and after the end of intervention
Method of measurement
 blood test

2

Description
 Low density lipoprotein
Timepoint
 before intervention and after the end of intervention
Method of measurement
 blood test

3

Description
 High density lipoprotein
Timepoint
 before intervention and after the end of intervention
Method of measurement
 blood test

4

Description

Alanine aminotransferase

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

5

Description

Blood urea nitrogen

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

6

Description

Glycosylated hemoglobin

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

7

Description

Triglyceride

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

8

Description

Complete Blood Count

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

9

Description

Fasting blood sugar

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

10

Description

Creatinine

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

11

Description

Partial thromboplastin time

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

12

Description

Prothrombin Time

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

13

Description

International Normalized Ratio (INR)

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

14

Description

Cholesterol

Timepoint

before intervention and after the end of intervention

Method of measurement

blood test

Intervention groups

1

Description

Intervention group: In the first intervention group, standardized treatment and physiotherapy, and also Dorema ammoniacum gum with a daily dose of one gram is given as an oral capsule, twice a day for one month.

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group receives the standard treatment and physiotherapy and also acupuncture treatment provided by an acupuncturist. The number of acupuncture sessions is twelve 30 minute sessions, three times a week.

Category

Treatment - Drugs

3

Description

Control group: In the control group, standard treatment

and physiotherapy are received.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Neurology, Ghaem Hospital

Full name of responsible person

Dr. Kavian Ghandehari

Street address

Ghaem Hospital, Ghaem Educational and Research and Therapeutic Center, Ahmad Abad Ave., Dr Shariati Square (Taghi Abad)

City

Mashhad

Province

Razavi Khorasan

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91766-99199

Phone

+98 51 3840 0001

Email

GhandehariK@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Vice Chancellor for Research of Medical University of Mashhad, Qaryashi Building, Daneshgah St.

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Vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Mehrpour

Position

Persian Traditional Medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Traditional Medicine and Supplement, Mashhad University of Medical Sciences, Ferdowsi University, Azadi Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Bahrami Taghanaki

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Faculty of Traditional Medicine and Supplement, Mashhad University of Medical Sciences, Ferdowsi University, Azadi Square

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Email

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Mehrpour

Position

Persian Traditional Medicine Student

Latest degree

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Other areas of specialty/work

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University, Azadi Square

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Mashhad

Province

Razavi Khorasan

Postal code

917794-8564

Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available