

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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)

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

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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**

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**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

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## 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**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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University, Azadi Square

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**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