Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effect of high dose oral Acetyl-L-carnitine and placebo on serum level of inflammatory cytokines in patients with ischemic stroke: a double-blind randomized clinical trial

Protocol summary

Study aim
Determination of the Effect of High-Dose Acetyl- L-Carnitine as an Adjuvant Therapy in Reducing Inflammation in Ischemic Stroke Patients.

Design
This a double-blind randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
This study was conducted as a clinical, randomized, and double blind clinical trial on patients with ischemic stroke referred to Farshchian Sina Hospital in Hamedan. The researcher and participants were blinded.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: aged 18 to 85 years; focal neurological disorder;Ischemic stroke; Non-pregnancy and lactation; Hospitalization within the first 24 hours after stroke; ischemic stroke for the first time. Exit criteria: Evidence on acute or chronic intracerebral hemorrhage and brain aneurysm;The existence of any other etiology other than ischemia.

Intervention groups
Intervention group: Routine stroke treatment plus oral Acetyl-L-carnitine capsule, 500 mg, every 8 hours, for 3 days. Control group: Routine stroke treatment plus oral placebo, every 8 hours, for 3 days.

Main outcome variables
Serum level of IL-6,NSE,TNF-alpha,ICAM-1

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150629022965N14**
Registration date: **2018-04-21, 1397/02/01**
Registration timing: **registered_while_recruiting**
Last update: **2018-04-21, 1397/02/01**
Update count: **0**

Registration date
2018-04-21, 1397/02/01

Registrant information

Name
Maryam Mehrpooya

Name of organization / entity
School of Pharmacy,Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-20, 1396/12/29

Expected recruitment end date
2019-05-21, 1398/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of high dose oral Acetyl-L-carnitine and placebo on serum level of inflammatory cytokines in patients with ischemic stroke: a double-blind randomized clinical trial

Public title

Effect of high dose oral Acetyl-L-carnitine on ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 18 to 85 years focal neurological disorder Clinical diagnosis of hemispheric acute ischemic stroke Radiological findings in MRI and CT scan consistent with clinical diagnosis of acute hemispheric stroke No other inflammatory disease at same time Not using other drugs that alter the level of outcomes of this study no Pregnancy and lactation Patients who have been admitted for the first 24 hours after the stroke. Patients who have had an ischemic stroke for the first time.

Exclusion criteria:

Existing evidence show acute or chronic intracerebral hemorrhage and brain aneurysm The presence of any other etiology except ischemia The presence of any cognitive or behavioral impairment that leads to a patient's lack of cooperation

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

School of Pharmacy, Hamedan University of Medical Sciences, in front of Mardom park, Shahid Fahmide boulevard

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Hamedan

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Hamadan

Postal code

6517838678

Approval date

2018-03-09, 1396/12/18

Ethics committee reference number

IR.UMSHA.REC.1396.873

Health conditions studied

1

Description of health condition studied

ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

serum level of IL-6

Timepoint

before intervention and 3 days after intervention

Method of measurement

ELISA kit

2

Description

serum level of TNF-alpha

Timepoint

before intervention and 3 days after intervention

Method of measurement

ELISA kit

3

Description

serum level of NSE

Timepoint

before intervention and 3 days after intervention

Method of measurement

ELISA kit

4

Description

serum level of ICAM-1

Timepoint

before intervention and 3 days after intervention

Method of measurement

ELISA kit

Secondary outcomes

1

Description

side effects

Timepoint

3 days after intervention

Method of measurement

Clinical examination

Intervention groups

1

Description

Control group: In the control group, patients will receive placebo at the dose of 1 g, three times a day (every 8 hours) for 3 days in addition to the standard treatment.

Category

Placebo

2

Description

Intervention group: In the intervention group, patients will receive oral Acetyl-l-Carnitine, one 500mg capsule, at the dose of 1 g three times a day (every 8 hours) for 3 days in addition to the standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Farshchian Sina Hospital

Full name of responsible person

Maryam Mehrpooya

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Farshchian Sina Hospital, Mirzadeh Eshghi St, Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Mehrpooya

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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