

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparing the effect of protein whey, lipoic acid and protein whey in combination with lipoic acid on inflammatory and antioxidant markers and clinical prognosis among acute ischemic stroke patients.

Protocol summary

Summary

This study is designed to evaluate effects of protein whey, lipoic acid and protein whey in combination with lipoic acid on inflammatory and biochemical markers, clinical and functional outputs. Patients with definite ischemic stroke with first admission to Emam Reza Hospital will be the target population for study. In this mono center, double blind study, 120 patients with ischemic stroke will be randomized by block randomization method. Patients regarding inclusion criteria including age more than 40 years old; hospitalized with definite diagnosis of acute ischemic stroke; NIHSS \leq 20 and starting of tube feeding within 48 hours after admission will be randomize to receive 1) nasogastric feeding with routine hospital feeding(control group), 2) routine hospital feeding plus formula containing 20 gr of protein whey (whey group) or 3) another isocaloric and isonitrogenous formula containing 1200mg of lipoic acid (LA group) and 4) receive routine hospital feeding plus 20 gr of protein whey as well as 1200mg of lipoic acid (whey + LA group) for 21 days. Patients with vegetative ischemic stroke, TPA injection, history of chronic diseases will be excluded from study. The primary endpoints of the study are changes in the serum levels of C-reactive protein (CRP), interleukin 6 (IL-6), albumin level, tumor necrosis factor- α (TNF- α) and total antioxidant capacity. The secondary endpoints are NIHSS and MRS and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428450N1**
Registration date: **2016-06-28, 1395/04/08**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-28, 1395/04/08

Registrant information

Name

Mohammad Khalili

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Tabriz university of Medical Sciences.

Expected recruitment start date

2016-08-01, 1395/05/11

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of protein whey, lipoic acid and protein whey in combination with lipoic acid on inflammatory and antioxidant markers and clinical prognosis among acute ischemic stroke patients.

Public title

The effects of protein whey, lipoic acid and protein whey in combination with lipoic acid among acute ischemic stroke patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age more than 40 years old; hospitalized with definite diagnosis of acute ischemic stroke; NIHSS \leq 20; start of tube feeding in 48 hours after admission. Exclusion criteria: vegetative ischemic stroke; TPA injected patients; history of chronic diseases (renal failure needing dialysis at admission time); hepatic cirrhosis and liver diseases; chronic respiratory disease; heart failure; history of cancer; epilepsy and GI bleeding; uncontrolled diabetes; history of myocardial infarction in the past 3 months; enteral feeding less than 10 days; alcohol and opioid consumption.

Age

From **41 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

blocked randomization method will be used

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of medical Sciences

Street address

Tabriz , Iran

City

Tabriz

Postal code

Approval date

2016-04-30, 1395/02/11

Ethics committee reference number

IR.TBZMED.REC.1395.52-55

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

163.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

serum albumin

Timepoint

base line and 3 weeks later

Method of measurement

Laboratory test, spectrophotometric

2

Description

total antioxidant capacity

Timepoint

before intervention and 3 weeks after intervention

Method of measurement

Laboratory test, ELIZA

3

Description

C reactive protein

Timepoint

before intervention and 3 weeks after intervention

Method of measurement

Laboratory test, ELIZA

4

Description

\uparrow tnf-a

Timepoint

before intervention and 3 weeks after intervention

Method of measurement

Laboratory test, ELIZA

5

Description

IL-6

Timepoint

before intervention and 3 weeks after intervention

Method of measurement

Laboratory test, ELIZA

Secondary outcomes

1

Description

NIHSS

Timepoint

before intervention, 3 weeks after intervention

Method of measurement

observation with physical examination

2

Description

MRS

Timepoint

before intervention, 3 weeks after intervention and 3 months after intervention

Method of measurement

observation with physical examination

3

Description

Quality of life

Timepoint

3 weeks after intervention

Method of measurement

SF-36 Questionnaire

Intervention groups

1

Description

Control group: patients in this group receive routine hospital feeding.

Category

Treatment - Other

2

Description

Intervention group 1: patients in this group receive daily 20 gr of protein whey in addition to routine hospital feeding.

Category

Treatment - Other

3

Description

Intervention group 2: patients in this group will consume 1200 mg/day in addition to routine hospital feeding and 1 hour after noon feeding.

Category

Treatment - Other

4

Description

Intervention group 3: patients in this group will consume daily dose of 20 gr of protein whey plus 1200 mg of lipoic acid in addition to routine hospital feeding.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dr. Mohammad Khalili

Street address

Neurology ICU unit, flour1, Emam Reza Hospital, Attar Neishabouri avenue, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellaor of research and technology , Tabriz university of medical science

Full name of responsible person

Dr. Mohammad reza Rashidi

Street address

Vice chancellaor of research and technology , Tabriz University of Medical Science

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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

Vice chancellaor of research and technology , Tabriz university of medical science

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad khalili

Position

Ph.D/Assistant professor

Other areas of specialty/work

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Web page address**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