Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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<=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-a (TNF-a) 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

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Mohammad Khalili
Name of organization / entity
Tabriz 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 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 yars old; hospitalized with definite diagnosis of acute ischemic stroke; NIHSS<=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, spectophotometric

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
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, Atttar 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
City
Tabriz
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
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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