Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the effect of IMOD (Setarud) on the National Institute of Health Stroke Scale (NIHSS) in acute ischemic stroke

Protocol summary

Summary

The aim of this study is to investigate the effect of IMOD (Setarud) on clinical signs and symptoms and inflammatory factors in patients with acute ischemic stroke. In this parallel randomized controlled trial patients with acute ischemic stroke will be randomized into two groups during first 24 hours of symptom onset. Patients with prior neurological deficit of any cause, cancer or any other severe disease, rapidly improving symptoms prior to intervention, NIHSS less than 5 at presentation and concurrent immunosuppressive/immunomodulator drug use will be excluded. Patients of control group will receive routine treatment based on ward protocol and patients of intervention group will receive routine treatment plus IMOD infusion for total seven days. Serum levels of TNF-alpha, IL-1 and IL-6 and WBC, platelet and CRP will be measured at first, fourth and seventh days and NIHSS & MRS will be assessed at first and seventh days and third month after disease presentation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108202195N2**
Registration date: **2011-10-15, 1390/07/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-15, 1390/07/23

Registrant information

Name

Mehdi Farhoudi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

1- Neuroscience Research Center, Vice chancellor for research, Tabriz University of Medical Sciences 2- Pars Roos Company

Expected recruitment start date

2011-10-12, 1390/07/20

Expected recruitment end date

2012-01-10, 1390/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of IMOD (Setarud) on the National Institute of Health Stroke Scale (NIHSS) in acute ischemic stroke

Public title

Effect of IMOD in the treatment of stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with acute ischemic stroke (based on clinical and imaging findings) Exclusion criteria: age less than 18years or more than 80 years, prior neurological deficit of any cause, cancer or any other severe disease, rapidly improving symptoms prior to intervention, NIHSS less than 5 at disease

presentation, symptom onset less than 3 hours or more than 24 hours, no informed consent, concurrent immunosuppressive / immunomodulator drug use.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht St., Tabriz, Iran

City

Tabriz

Postal code

Approval date

2011-08-02, 1390/05/11

Ethics committee reference number

5/4/3690

Health conditions studied

1

Description of health condition studied

Acute Ischemic Stroke

ICD-10 code

I63

ICD-10 code description

occlusion and stenosis of cerebral and precerebral arteries, resulting in cerebral infarction

Primary outcomes

1

Description

Neurological outcome of Acute Ischemic Stroke

Timepoint

Prior to intervention, days 7 & 90 after symptom onset

Method of measurement

National Institute of Health Stroke Scale (NIHSS)

2

Description

Functional outcome of Acute Ischemic Stroke

Timepoint

Prior to intervention, days 7 & 90 after symptom onset

Method of measurement

Modified Rankin Scale (MRS)

3

Description

Arm Motor deficit following Acute Ischemic Stroke

Timepoint

Prior to intervention, days 7 & 90 after symptom onset

Method of measurement

National Institute of Health Stroke Scale (NIHSS)

4

Description

Sensory deficit following Acute Ischemic Stroke

Timepoint

Prior to intervention, days 7 & 90 after symptom onset

Method of measurement

National Institute of Health Stroke Scale (NIHSS)

5

Description

Facial palsy following Acute Ischemic Stroke

Timepoint

Prior to intervention, days 7 & 90 after symptom onset

Method of measurement

National Institute of Health Stroke Scale (NIHSS)

6

Description

Leg Motor deficit following Acute Ischemic Stroke

Timepoint

Prior to intervention, days 7 & 90 after symptom onset

Method of measurement

National Institute of Health Stroke Scale (NIHSS)

7

Description

Best Language following Acute Ischemic Stroke

Timepoint

Prior to intervention, days 7 & 90 after symptom onset

Method of measurement

National Institute of Health Stroke Scale (NIHSS)

8

Description
Dysarthria following Acute Ischemic Stroke
Timepoint
Prior to intervention, days 7 & 90 after symptom onset
Method of measurement
National Institute of Health Stroke Scale (NIHSS)

Secondary outcomes

1

Description
IL-1
Timepoint
Prior to intervention and days 4 & 7 after symptom onset
Method of measurement
ELISA

2

Description
IL-6
Timepoint
Prior to intervention and days 4 & 7 after symptom onset
Method of measurement
ELISA

3

Description
Relative Frequency of Hemorrhagic Complications
Timepoint
7th day after symptom onset
Method of measurement
Spiral Brain CT scan

4

Description
Relative Frequency of Infectious Complications
Timepoint
7th day after symptom onset
Method of measurement
Blood Culture; Urine Culture; CXRay alterations

5

Description
Survival
Timepoint
90th day after symptom onset
Method of measurement
Kaplan-Meier survival curves

6

Description
TNF-alpha
Timepoint
Prior to intervention and days 4 & 7 after symptom onset
Method of measurement
ELISA

7

Description
WBC
Timepoint
Prior to intervention and days 4 & 7 after symptom onset
Method of measurement
Cell count

8

Description
platelet
Timepoint
Prior to intervention and days 4 & 7 after symptom onset
Method of measurement
Cell count

Intervention groups

1

Description
Routine treatment for Acute Ischemic Stroke (based on ward protocol) plus Daily infusion of IMOD (Herbal extract of Tanacetum Vulgare, Rosa Canina and Urtica dioica enriched with Selenium, 120 mg/4cc) 8cc at first day & 12cc at following days in serum DW5 over 30min for total 7days
Category
Treatment - Drugs

2

Description
Routine treatment for Acute Ischemic Stroke (based on ward protocol)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Medical Center
Full name of responsible person
Dr. Mehdi Farhoudi
Street address
Neurosciences Research Center, Gholghasht Street
City
Tabriz

2

Recruitment center
Name of recruitment center

Razi Medical Center

Full name of responsible person
Dr. Mahdi Najafi Nesheli

Street address
El-Gholi Avenue

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person
Dr Mohammadreza Rashidi

Street address
Tabriz University of Medical Sciences, Golgasht St.

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity
Pars Roos Co.

Full name of responsible person
Dr. Ata Mahmoodpoor

Street address
No. 568, 13th Alley, Hormozan St., Shahrak-e-Ghods

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Pars Roos Co.

Proportion provided by this source

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
Neuroscience Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Dr Mehdi Farhoudi

Position
Head of NSRC Tabriz University of Medical Sciences

Other areas of specialty/work

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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