

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Granulocyte-Colony Stimulating Factor Treatment for Acute Ischemic Stroke: A Randomized Control Trial Study Assessing Clinical and Radiological Responses

Protocol summary

Summary

Objectives: This project is a Triple- Blind Randomized Control Trial Study assessing clinical and radiological responses in acute ischemic stroke referred to Imam khomeini Hospital. **Design:** Neural stem cells and mature neurons have G-CSF receptor. Stimulation of G-CSF receptor leads to inhibition of apoptosis, neuroprotection against ischemia and cytotoxic agents, and stimulation of bone marrow and neural stem cells. Several experimental models confirmed above findings which results in this hypothesis that G-CSF may be effective in ischemic stroke. Confirmation of this idea can be an effective step in the treatment of cerebral ischemia. **Setting and conduct:** this study is a triple-blind randomized clinical trial which evaluates therapeutic effects of G-CSF in acute stroke patients. **Interventions:** After verifying the consensus form, intervention group and control group will receive G-CSF and placebo, respectively. All patients will receive standard treatments verifying by accepted guidelines. **Participants including major eligibility criteria:** Inclusion Criteria: Acute ischemic stroke in the territory of middle cerebral artery which is confirmed by imaging. In addition, less than 24 hours from the beginning of stroke has been lost. Exclusion criteria include: Hypersensitivity to E coli proteins or G-CSF; History of cancer; History of chronic diseases; More than 2/3 of MCA territory; Pregnancy; and lacunar infarction. **Intervention:** Drug and placebo, and **Sampling Major outcome:** clinical (Bartle scale), radiological (volume of lesion), and biochemical (IL-6 ...) indexes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208081584N2**

Registration date: **2012-09-16, 1391/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

Name

Mohammad Hossein Harirchian

Name of organization / entity

Tehran University of Medical Science, Iranian Center of Neurological Research

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Recruitment status

Recruitment complete

Funding source

Teharn University of Medical Sciences and Pooyesh Darou Company are sponsors of this clinical trial.

Expected recruitment start date

2012-09-01, 1391/06/11

Expected recruitment end date

2014-09-01, 1393/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Granulocyte-Colony Stimulating Factor Treatment for Acute Ischemic Stroke: A Randomized Control Trial Study Assessing Clinical and Radiological Responses

Public title

Granulocyte-Colony Stimulating Factor Treatment for Acute Ischemic Stroke: A Randomized Control Trial Study Assessing Clinical and Radiological Responses

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age: 40-80; stroke was confirmed by DWI; less than 24 hours of beginning of stroke; NIHSS scale: 4-24; Stroke in MCA territory Exclusion criteria: hypersensitivity to E coli proteins or G-CSF; History of cancer; History of severe renal, liver and hematological diseases; More than 2/3 of MCA territory; Pregnancy; The patient is candidate for rTPA; Acute ICH; Lacunar infarction

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, 5th floor, Ghods St, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

90-04-54-15797-53565

Health conditions studied

1

Description of health condition studied

Acute Ischemic Stroke

ICD-10 code

G46.0

ICD-10 code description

A stroke is caused by the interruption of the blood supply to the brain, usually because a blood vessel is blocked by a clot. This cuts off the supply of oxygen and nutrients, causing damage to the brain tissue.

Primary outcomes

1

Description

Clinical sign and symptoms

Timepoint

first week, 2nd week, 1st and 2nd and 3rd months

Method of measurement

NIHSS scale, Barthel Index Scale Score, modified rankin scale

Secondary outcomes

1

Description

Lesion volume

Timepoint

one week

Method of measurement

Brain MRI(DWI and PWI)

Intervention groups

1

Description

Case group receives G-CSF, 10 microgram per kilogram of body weight subcutaneously. However the first dose will be prescribed via intra venous line.

Category

Treatment - Drugs

2

Description

Control group will receive placebo (normal saline, 0.1 ml per kg of body weight). Participation in the study doesn't produce any avoidance for receiving standard treatment of stroke.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Center of Neurological Researches

Full name of responsible person

Dr Mohammad Hossein Harirchian

Street address

Iranian Center of Neurological Researches, Imam Khomeini Hospital, Blvd Keshavarz, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Fotuhi

Street address

Vice chancellor for research, Tehran University of Medical Sciences, Ghods Street, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number**

90-04-54-15797

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

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Pooyesh darou Company

Full name of responsible person

Dr Tabatabaee

Street address

Pooyesh darou, on the opposite side of Center of Growth and Technology, after unknown martyr highway, north kargar St, Tehran, Iran

City

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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

Pooyesh darou Company

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

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Full name of responsible person

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Position

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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