

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Granulocyte Colony Stimulating Factor (GCSF) in the treatment of Amyotrophic Lateral Sclerosis (ALS) patients referred to Tehran Imam Khomeini and Shariati hospital centers in 2012.

Protocol summary

Summary

The aim of study is to evaluate the effect off Granulocyte Colony Stimulating Factor (GCSF) in the treatment of Amyotrophic Lateral Sclerosis (ALS) patients. program: multicenter, double blind, controlled, randomized clinical trial. sample: patients with ALS referred to Tehran Imam Khomeini and Shariati hospital centers. major inclusion criteria: age between 18 and 85, definite or probable ALS, maximum 2 years from initiation of symptoms to study entry, mild to moderate disability according to ALSFRS-r. major exclusion criteria: pregnancy or lactation, neoplasia, mieloproliferative or hematologic disorders, active immunological disease, splenomegaly, liver or renal or heart disease, HIV positive, significant cognitive disorder, hypersensitivity to GCSF sample size: 40 patients interventions: Granulocyte Colony Stimulating Factor 10 microgram/ kg/ day or normal saline 0.01 ml/kg/day subcutaneously time of intervention: for 5 days Primary outcome measure: patient`s function according to ALSFRS-r criteria. Secondary outcome measure:changing in mobilizing factors of bone marrow stem cells including CD34 count,amplitude of compound muscle action potential in ulnar and proneal nerve, quality of life by ALSAQ-40 questioner, muscle power by Manual Muscle Test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207238509N2**
Registration date: **2012-08-17, 1391/05/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-08-17, 1391/05/27

Registrant information

Name

Nasibeh Amirzargar

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iranian Neurology Research Center of Tehran University of Medical Sciences
Immunology Research Center of Tehran University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Granulocyte Colony Stimulating Factor (GCSF) in the treatment of Amyotrophic Lateral Sclerosis (ALS) patients referred to Tehran Imam Khomeini and Shariati hospital centers in 2012.

Public title

The effect of Granulocyte Colony Stimulating Factor in

treatment of Amyotrophic Lateral Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age between 18 and 85, definite or probable ALS according to revised El Escorial criteria, maximum 2 years from initiation of symptoms to study entry, mild to moderate disability according to ALSFRS-r, permanent use of rilosole for at least 30 days. exclusion criteria: familial ALS, pregnancy or lactation, neoplasia, mieloproliferative or hematologic disorders, active immunological disease, splenomegaly, liver or renal or heart disease, HIV positive, FVC below 50%, significant cognitive disorder, hypersensitivity to GCSF

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences- research center

Street address

number 1- Ghods Avenue- Keshavarz Boulevard- central building of Tehran University of Medical Sciences

City

tehran

Postal code

Approval date

2012-07-18, 1391/04/28

Ethics committee reference number

91-01-54-17265-58480

2

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences- research assistant

Street address

number 16, Poursina Street, 16th Azar Avenue, Keshavarz Boulevard

City

tehran

Postal code

Approval date

2012-08-06, 1391/05/16

Ethics committee reference number

91-971-130-3

Health conditions studied

1

Description of health condition studied

amyotrophic lateral sclerosis

ICD-10 code

VI

ICD-10 code description

Diseases of the nervous system

Primary outcomes

1

Description

patient`s function

Timepoint

before intervention and 3 months after intervention

Method of measurement

ALS functional rating scale questioner

Secondary outcomes

1

Description

mobilizing bone marrow stem cells

Timepoint

before intervention and day 3 and 6 after initiation of intervention

Method of measurement

CD34 count

2

Description

amplitude of compound muscle action potential in ulnar and proneal nerve

Timepoint

before intervention and 3 months after initiation of intervention

Method of measurement

EMG-NCV

3

Description

quality of life

Timepoint

before intervention and 3 months after intervention

Method of measurement

ALSAQ-40 questioner

4

Description

muscle power

Timepoint

before intervention and 3 months after intervention

Method of measurement

Manual muscle test

Intervention groups

1

Description

normal saline 0.01 ml/kg/day for 5 days subcutaneously

Category

Placebo

2

Description

Granulocyte Colony Stimulating Factor 10 microgram/ kg/ day for 5 days subcutaneously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital, Iranian neurology research center

Full name of responsible person

Dr. Mohammad Hossein Harirchian

Street address

Iranian neurology research center, Imam Khomeini hospital, Gharib Street, Keshavarz Boulevard

City

tehran

2

Recruitment center

Name of recruitment center

department of neurology in Shariati hospital

Full name of responsible person

dr. Shahriyar Nafisi

Street address

department of neurology, Shariati hospital, North Karegar Avenue

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian neurology research center of Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Harirchian

Street address

Iranian neurology research center, Imam Khomeini hospital

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian neurology research center of 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

immunology research center of Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Amirzargar

Street address

immunology research center in Tehran university of medical sciences

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

immunology research center of 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

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian neurology research center of Tehran
University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hossein Harirchian
Position
manager of neurology department of Tehran
University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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