

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness Study Comparing Granulocyte colony-stimulating factor (GCSF) with Placebo for Improvement of Sensory, Motor and Sphincter Function in Patients with Spinal cord Injury

Protocol summary

Summary

The goal of this study was to evaluate effect of Granulocyte colony-stimulating factor (GCSF) Treatment on Sensory, Motor and Sphincter Function in Patients with Spinal cord Injury. This double blind randomized clinical trial conducted in Brain and Spinal Injury Research center (Affiliated to Tehran University of Medical Sciences). 60 patients with spinal cord injury, according to inclusion criteria, will be enrolled. Patients will be divided to intervention or control group by means of computer generated randomization by a blind technician. Another blind technician will label 300 mcg vials of Granulocyte colony stimulating factor and placebo (normal saline) through simple random allocation. 300 mcg vial GCSF and placebo are similar due to shape, color and volume. At the beginning of the study neurological status of the patients will be assessed (according to the American Spinal Injury Association (ASIA) impairment scale) and complete blood count test will be performed. All patients will be asked to fill the SCIM questionnaire (Spinal Cord Independence Measure III), SF36 questionnaire (for evaluating the patients quality of life) and FSFI or IIEF questionnaire (for evaluating the patients sexual life). Subcutaneous administration of GCSF or placebo will be performed for 5 days. CBC test will be performed 3 days after last injection. Follow up evaluations will be done on 1st, 3rd, 6th and 12th months of study. (CBC test/SCIM, ASIA, SF36 ,IIEF, FSF and physical examination to find any probable side effects). Primary outcomes will be the sensory level score and motor score according to the American Spinal Injury Association (ASIA) impairment scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108297441N1**

Registration date: **2012-06-05, 1391/03/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-05, 1391/03/16

Registrant information

Name

Hooshang Saberi

Name of organization / entity

Brain and Spinal Injury research center, Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

00982166581560 - 00982166581561

Email address

saberih@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Brain And Spinal Injury Research center, Tehran University of Medical Sciences

Expected recruitment start date

2011-11-02, 1390/08/11

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness Study Comparing Granulocyte colony-stimulating factor (GCSF) with Placebo for Improvement of Sensory, Motor and Sphincter Function in Patients with Spinal cord Injury

Public title

The Effect of Granulocyte colony-stimulating factor (GCSF) Treatment for Improvement of Sensory, Motor and Sphincter Function in Patients with Spinal cord Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients must be able to give voluntary consent; 2. Age between 20 to 40 years old; 3. Time between injury and enrollment greater than 1 year; 4. No evidence of cord compression, disc herniation, cord atrophy and angulation deformity on the performed MRI; 5. No evidence of lower motor neuron injury; 6. No evidence of ossification; 7. Optimized SCIM questionnaire score; 8. Not using indwelling catheterization; 9. No evidence of any other systemic or psychological disorder; 10. No evidence of bedsores; 11. Normal Complete Blood Count; 12. Evidence of incomplete spinal cord injury according to the American Spinal Injury Association Impairment Scale. Exclusion criteria: 1. Evidence of drug side effects; 2. Past history of hematologic disorders in patients or patients' first degree relatives.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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**

Ethics committee of Tehran University of medical sciences

Street address

Tehran University of medical sciences, Poursina street

City

Tehran

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

90-02-85-14-602-47731

Health conditions studied**1****Description of health condition studied**

traumatic spinal cord injury

ICD-10 code

V01 - X59

ICD-10 code description

Accidents

Primary outcomes**1****Description**

sensory level score, motor score

Timepoint

before the intervention, 1st, 3rd, 6th and 12th months of study

Method of measurement

according to American Spinal Injury Association (ASIA) impairment scale

Secondary outcomes**1****Description**

independent life ability

Timepoint

before the intervention, 1st, 3rd, 6th and 12th months of study

Method of measurement

Spinal Cord Independence Measure III

Intervention groups**1****Description**

in the intervention group subcutaneous administration of 300 mcg GCSF will be performed for 5 days

Category

Treatment - Drugs

2**Description**

in the control group subcutaneous administration of placebo (normal saline) will be performed for 5 days

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Brain and Spinal Injury Research Center
Full name of responsible person
Dr. Hooshang Saberi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Brain and Spinal Injury Research Center, Tehran
university of medical sciences
Full name of responsible person
Hooshang Saberi
Street address
Brain and Spinal Injury 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

Brain and Spinal Injury Research Center, Tehran
university of medical sciences

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
Tehran University of Medical Sciences
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Position
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Person responsible for scientific inquiries

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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