Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 bedsore; 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
Full name of responsible person
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Person responsible for updating data

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Web page address

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