

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

A comparison between therapeutic effect of granulocyte colony-stimulating factor and methylprednisolone on sensory and motor function in patients with acute traumatic spinal cord injury

Protocol summary

Summary

This study aims to evaluate and compare the therapeutic effect of granulocyte colony-stimulating factor (G-CSF) and methylprednisolone on sensory and motor function in patients with acute traumatic spinal cord injury. In a randomized clinical trial patients between 18 to 65 years old with acute (48 hours after trauma) traumatic spinal cord injury, will be enrolled according to inclusion criteria. Before the intervention spinal cord injury grade will be assessed according to ASIA impairment scale (AIS) and Sensory and motor function score will be assessed according to American Spinal Injury Association (ASIA) scoring system. Ninety two patients will be divided into intervention or control group in a randomized block design. The Intervention group will be treated by intravenous infusion of 10 microgram/kg/day of G-CSF for 5 consecutive days and the control group will receive standard treatment of high dose of methylprednisolone. Follow up evaluations will be done on 1 week after the intervention, 3 months after the intervention and 6 months after the intervention.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201504077369N2**
Registration date: **2015-08-17, 1394/05/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-17, 1394/05/26

Registrant information

Name

Firouz Behboudi

Name of organization / entity

Gilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Guilan University of Medical Sciences

Expected recruitment start date

2013-05-29, 1392/03/08

Expected recruitment end date

2014-05-29, 1393/03/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between therapeutic effect of granulocyte colony-stimulating factor and methylprednisolone on sensory and motor function in patients with acute traumatic spinal cord injury

Public title

Therapeutic effect of granulocyte colony-stimulating factor in patients with acute traumatic spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Acute traumatic spinal cord injury; Age between 18 to 65 years old Exclusion criteria: Presence of intracranial lesions such as tumor, infection, ischemia or trauma; Past history of massive blood loss with transfusion; Past history of leukopenia or thrombocytopenia; Past history of hepatic or renal dysfunction; Past history of sever heart failure; Presence of splenomegaly or past history of it; Any evidence of malignancy during past 5 years; Pregnancy or lactation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The patients are divided into intervention or control groups by randomized block design.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology of Guilan University of Medical Sciences, West Shahid Beheshti Blv, in front of Bank Sepah, Top floor of Iran Radiator agency, Rasht, Iran

City

Rasht

Postal code

Approval date

2015-02-24, 1393/12/05

Ethics committee reference number

1930596707

Health conditions studied

1

Description of health condition studied

Traumatic spinal cord injury

ICD-10 code

V01-V99

ICD-10 code description

Transport accidents

2

Description of health condition studied

Traumatic spinal cord injury

ICD-10 code

W00-X59

ICD-10 code description

Other external causes of accidental injury

3

Description of health condition studied

Traumatic spinal cord injury

ICD-10 code

S24.1

ICD-10 code description

Other and unspecified injuries of thoracic spinal cord

4

Description of health condition studied

Traumatic spinal cord injury

ICD-10 code

S14.1

ICD-10 code description

Other and unspecified injuries of cervical spinal cord

5

Description of health condition studied

Traumatic spinal cord injury

ICD-10 code

T91.3

ICD-10 code description

Sequelae of injury of spinal cord

Primary outcomes

1

Description

Spinal cord injury grade

Timepoint

Before the intervention, 1 week after the intervention, 3 months after the intervention and 6 months after the intervention

Method of measurement

AIS grading system

2

Description

Sensory and motor function score

Timepoint

Before the intervention, 1 week after the intervention, 3 months after the intervention and 6 months after the intervention

Method of measurement

ASIA scoring system

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intravenous infusion of 10 microgram/kg/day G-CSF for 5 consecutive days

Category

Treatment - Drugs

2

Description

Methylprednisolone is given as an initial intravenous bolus of 30 mg/kg administered over a period of 15 minutes. This is followed 45 minutes later by a 5.4 mg/kg per hour continuous infusion of methylprednisolone. If treatment is initiated within 3 hours of injury, the infusion is continued for 23 hours; if treatment is begun between 3 to 8 hours after injury, the infusion is continued for 47 hours (for a total of 48 hours).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Poursina Hospital

Full name of responsible person

Siavash Dehghani

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of

Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Vice Chancellor for Research and Technology of
Guilan University of Medical Sciences, West Shahid
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Radiator agency, Rasht, Iran

City

Rasht

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 and Technology of Guilan
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

Guilan University of Medical Sciences

Full name of responsible person

Siavash Dehghani

Position

Senior Resident of Neurosurgery

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