

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Synchronic Administration of Vitamin D and Progesterone on Outcome of Patients with Acute Spinal Cord Injury; A Randomized, Double Blind, Placebo Controlled Study

Protocol summary

Summary

The aim of the present study is to determine the effects of vitamin D and progesterone administration on outcome of patients with acute traumatic spinal cord injury between 18 and 65 years of age who are referred within 8 hours after injury. We will exclude those receiving maintenance steroids for other reasons; those who had received more than 100 mg of methylprednisolone or its equivalent before admission to the center; pure sensory loss; complete motor deficit; cauda equina only and gunshot wounds. All the patients will receive standard treatment with methylprednisolone (30 mg/kg intravenously as bolus dose and 15 mg/kg each 3 hours till 24 hours). Patients will be randomized using a computer-based random digit generator. Those assigned to treatment group will receive intramuscular injection of progesterone twice a day for 5 days in addition to oral vitamin D3 twice a day for 5 days on admission while those in placebo group will receive placebo injections and tablets in the same manner. Patients would not be aware of the medication they receive as treatment. The nurse prescribing the drug would also be blinded to ward the type of medication. Patients would be visited 24 hours, 6 days and 3 months later and would be assessed regarding International Standards for Neurological Classification of Spinal Cord Injury (ISCS). The scores would be compared between groups. The physician recording the outcome would be blinded toward the study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310082445N2**

Registration date: **2013-11-01, 1392/08/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-01, 1392/08/10

Registrant information

Name

Fariborz Ghaffarpasand

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Synchronic Administration of Vitamin D and Progesterone on Outcome of Patients with Acute Spinal Cord Injury; A Randomized, Double Blind, Placebo Controlled Study

Public title

Vitamin D and Progesterone for Acute Spinal Cord Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 65 years; giving informed written consents; traumatic acute spinal-cord injury; being randomized within 8 hours of the injury.

Exclusion criteria: Age less than 18 or more than 65 years; involvement of the nerve root; cauda equina only; gunshot wounds; life-threatening morbidity; those who were pregnant; addicted to narcotics; receiving maintenance steroids for other reasons; those who had received more than 100 mg of methylprednisolone or its equivalent, or 1 mg of naloxone before admission to the center; those in whom follow-up would be difficult; pure sensory loss; complete motor deficit; randomization >8 hours after injury.

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Prospective, Double Blind, Placebo Controlled

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan Medical School, Hezar Jarib Avenue

City

Isfahan

Postal code

Approval date

2012-06-13, 1391/03/24

Ethics committee reference number

391332

Health conditions studied

1

Description of health condition studied

Spinal cord injury

ICD-10 code

T02.1

ICD-10 code description

multiple fractures of spine, level unspecified

Primary outcomes

1

Description

Muscular force of the effected limbs

Timepoint

24-hour, 6 days, 3 months

Method of measurement

International Standards for Neurological Classification of Spinal Cord Injury

Secondary outcomes

1

Description

Sensory level

Timepoint

24-hour, 6 days, 3 months

Method of measurement

Pinprick and Light Touch

Intervention groups

1

Description

Intramuscular injection of 5 mg Progesterone twice daily up to 5 days + 0.5 mg Vitamin D3 orally twice daily for 5 days

Category

Treatment - Drugs

2

Description

Intramuscular injection of normal saline twice a day for 5 days + oral placebo tablets twice a day for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Ali Asna Ashari

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Peyman Adibi

Street address

Vice chancellor for research - Building No. 3 - Isfahan
University of Medical Sciences - Hezar Jarib Avenue

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Ali Asna Ashari

Position

Resident of Neurosurgery

Other areas of specialty/work

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Bahram Amin Mansour

Position

Professor of Neurosurgery

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Al-Zahra hospital - Sofeh Avenue

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Fax

Email

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