

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Effect of omega 3 fatty acid on bone formation and resorption markers in osteoporotic spinal cord injured patients

Protocol summary

Summary

The objective of this study is to evaluate the effect of omega 3 fatty acid on bone formation and resorption markers in osteoporotic spinal cord injured patients. Eighty spinal cord injured patients with osteoporosis who come to clinic of spinal injury repair research center receive an injection of vitamin D (300,000 IU). Then one month later, the patients will receive two supplements of Calcium-D capsule (containing 500 mg calcium and 200 IU vitamin D) as well as two capsules of omega 3 (600 mg) in the intervention group and placebo in the control group. Primary outcome measures are serum IL1, IL6, TNF α , b-ALP, OPG, NTx, RANKL, and osteocalcin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905102709N7**

Registration date: **2010-08-28, 1389/06/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-08-28, 1389/06/06

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Brain and Spinal Injury Repair Research Center,
Endocrinology and Metabolism Research Center

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega 3 fatty acid on bone formation and resorption markers in osteoporotic spinal cord injured patients

Public title

Effect of omega 3 fatty acid on bone formation and resorption markers in osteoporotic spinal cord injured patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: no metabolic, malignant or kidney disorder, BMD: Z score <-2, normal TSH, LH, FSH, prolactin, and testosterone in men and normal prolactin, estradiol, LH, FSH, and TSH in women Exclusion criteria: pregnancy, lactation, presence of bone disease, hypersensitivity to fish or fish oil, hypertension

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

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

Ethic committee of School of Public health of Iran
University of Medical Sciences

Street address

No.52, Alvand avenue, Argantine aquare

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

1421

Health conditions studied

1

Description of health condition studied

Injury of spinal cord, level unspecified

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes

1

Description

IL-6

Timepoint

before intervention and four months after intervention

Method of measurement

ELIZA

2

Description

RANKL

Timepoint

before intervention and four months after intervention

Method of measurement

ELIZA

3

Description

Osteoprotegrin

Timepoint

before intervention and four months after intervention

Method of measurement

ELIZA

4

Description

b-ALP

Timepoint

before intervention and four months after intervention

Method of measurement

ELIZA

5

Description

TNF- α

Timepoint

before intervention and four months after intervention

Method of measurement

ELIZA

Secondary outcomes

empty

Intervention groups

1

Description

Injection of two vitamin D ampules (300,000 IU), then one month later, two supplements of Calcium-D capsule (containing 500 mg calcium and 200 IU vitamin D) as well as two capsules of omega 3 (600 mg) for four months

Category

Treatment - Drugs

2

Description

Injection of two vitamin D ampules (300,000 IU), then one month later, two supplements of Calcium-D capsule (containing 500 mg calcium and 200 IU vitamin D) as well as two placebo capsules for four months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Spinal Injury Repair Research Center

Full name of responsible person

Dr. Hadis Sabour

Street address

Brain and Spinal Injury Research Center, Imam Khomeini Hospital, Tehran University of Medical Sciences, Keshavarz Blvd., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Brain and Spinal Injury Repair Research Center-
Endocrine & Metabolism Research Institute

Full name of responsible person

dr.hadis sabour-Dr Ramin Heshmat

Street address

Keshavarz Blvd . Tehran 14185, IRAN-KARGAR BLVD-5
FLOOR-METABOLISM RESEARCH CENTER

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 Repair Research Center-Endocrine
& Metabolism Research Institute

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

Iran University of Medical Science

Full name of responsible person

Dr. Hadis Sabour

Street address

No.52, Alvand avenue, Argantine aquare

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Science

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

Brain and Spinal Injury Research Center,

Full name of responsible person

Dr. Hadis Sabour

Position

Nutrition group

Other areas of specialty/work**Street address**

Brain and Spinal Injury Research Center, Imam Khomeini Hospital, Tehran University of Medical Sciences, Keshavarz Blvd., Tehran

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+98 21 6658 1560

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hsabour@farabi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Brain and Spinal Injury Repair Research Center

Full name of responsible person

Dr Hadis Sabour

Position

MD-PHD-candidate

Other areas of specialty/work**Street address**

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City

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+98 21 6658 1560

Fax**Email**

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Web page address

Person responsible for updating data

Contact

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