# 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, TNFα, 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 Reseach 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
**City**
Tehran
**Postal code**
**Phone**
+98 21 6658 1560
**Fax**
**Email**
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**
5th floor, Brain and Spinal Injury Repair Research Center, Keshavarz Blvd.,
**City**
Tehran
**Postal code**
**Phone**
+98 21 6658 1560
**Fax**
**Email**

hsabour@farabi.tums.ac.ir

**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*