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

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

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  
Iran University of Medical Science

Proportion provided by this source  
empty

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 Repair Research Center, Imam Khomeini Hospital, Tehran University of Medical Sciences, Keshavarz Blvd., Tehran

Full name of responsible person  
Dr. Hadis Sabour

Position  
Nutrition group

Other areas of specialty/work

Street address  
5th floor, Brain and Spinal Injury Repair Research Center, Keshavarz Blvd., Tehran

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Fax

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hsabour@farabi.tums.ac.ir

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**Person responsible for scientific inquiries**

Contact

Name of organization / entity  
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Full name of responsible person  
Dr Hadis Sabour

Position  
MD-PHd-candidate

Other areas of specialty/work

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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