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, TNFa, 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

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<tr>
<td><strong>Recruitment center</strong></td>
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<tr>
<td><strong>Name of recruitment center</strong></td>
<td>Brain and Spinal Injury Repair Research Center</td>
</tr>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Dr. Hadis Sabour</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td>Brain and Spinal Injury Research Center, Imam Khomeini Hospital, Tehran University of Medical Sciences, Keshavarz Blvd., Tehran</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>Tehran</td>
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## Sponsors / Funding sources

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<td><strong>Sponsor</strong></td>
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<tr>
<td><strong>Name of organization / entity</strong></td>
<td>Brain and Spinal Injury Repair Research Center-Endocrine &amp; Metabolism Research Institute</td>
</tr>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Dr. Hadis Sabour</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td>Keshavarz Blvd. - Tehran 14185, IRAN-KARGAR BLVD-5 FLOOR-METABOLISM RESEARCH CENTER</td>
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<tr>
<td><strong>City</strong></td>
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<tr>
<td><strong>Grant name</strong></td>
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<td><strong>Grant code / Reference number</strong></td>
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<tr>
<td><strong>Is the source of funding the same sponsor organization/entity</strong>?</td>
<td>Yes</td>
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<td>Brain and Spinal Injury Repair Research Center-Endocrine &amp; Metabolism Research Institute</td>
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<td><strong>Type of organization providing the funding</strong></td>
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## Person responsible for general inquiries

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<td>Dr. Hadis Sabour</td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td>Nutrition group</td>
</tr>
<tr>
<td><strong>Other areas of specialty/work</strong></td>
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<td><strong>Phone</strong></td>
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<td><strong>Email</strong></td>
<td><a href="mailto:hsabour@farabi.tums.ac.ir">hsabour@farabi.tums.ac.ir</a></td>
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<td><strong>Web page address</strong></td>
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## Person responsible for scientific inquiries

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<td>MD-PH.D-candidate</td>
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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