

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of nutritional education of standard low fat and low calorie diets on reduction of risk factors of metabolic syndrome in comparison with control group in patients with chronic spinal cord injury

Protocol summary

Summary

There are limited studies that have evaluated the effect of nutritional educations in patients with spinal cord injury (SCI). The purpose of this study was to evaluate the effect of nutritional education in diagnostic criteria of metabolic syndrome in patients with chronic SCI. Main inclusion criteria were: age over 18 years, at least 2 years post injury duration, traumatic injury and BMI over 22. Exclusion criteria were disorders of calcium metabolism, bone diseases and metabolic disorders. The study population is patients with SCI that have been referred to Brain and Spinal Injury Research Center from August 2014 till September 2015. The sample size is 52 persons. Patients in intervention group will receive special nutritional education (standard diet of low fat and low calorie) for six months. Weight, blood pressure, lipid profile indexes, blood glucose and liver enzymes will be measured at baseline and after 3 and 6 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406215968N3**
Registration date: **2014-08-07, 1393/05/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-07, 1393/05/16

Registrant information

Name

Hadis Sabour

Name of organization / entity

Brain and Spinal Injury Research Center (BASIR)

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1560

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Recruitment status

Recruitment complete

Funding source

Brain and Spinal Injury Research Center (BASIR), Tehran
University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of nutritional education of standard low fat and low calorie diets on reduction of risk factors of metabolic syndrome in comparison with control group in patients with chronic spinal cord injury

Public title

Nutritional education effect on metabolic syndrome in patients with spinal cord injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are : Age above 18; Minimum time since injury of 2 years ; Traumatic injury; BMI higher than 22.
Exclusion criteria are: Pregnancy; lactation; Previous history of diseases that affect bone metabolism such as

Paget's disease; primary hyperparathyroidism; osteomalacia; Clinical hypocalcemia; hypophosphatemia; Consumption of medications like calcitonin, fluride, calciteriol, heparin, phenytoin, phenobarbital and estrogen in the past 6 months; Consumption of bisphosphonates or corticosteroids for more than 6 months; previous history of consumption of methotrexate or fluride; Recent consumption of medications (either synthetic or herbal) with anti-platelet activity, tetracyclin, magnesium or zinc supplements; Previous history of liver diseases or any symptoms indicating liver diseases based on screening laboratory tests; Previous history of fracture of femur or spine in the past year (unrelated to the trauma); Previous history of allergy to fish or fish oil; Anemia (confirmed by hemoglobin or hematocrit measurement); Hypertension

Age

From **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Boulevard Keshavarz, Ghods st.

City

Tehran

Postal code**Approval date**

2014-06-01, 1393/03/11

Ethics committee reference number

114766

Health conditions studied**1****Description of health condition studied**

Metabolic Syndrom

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome is a group of conditions that put you at risk for heart disease and diabetes. These conditions are high blood pressure high blood sugar levels high levels of triglycerides, a type of fat, in your blood low levels of hdl

2**Description of health condition studied**

Spinal Cord Injury

ICD-10 code

S24

ICD-10 code description

Injuries to the spinal cord (S24.0 and S24.1) refer to the cord level and not bone level injury, and can affect nerve roots at and below the level given

Primary outcomes**1****Description**

Cholesterol

Timepoint

At the baseline and then after 3 and 6 months

Method of measurement

Blood test

2**Description**

Triglyceride

Timepoint

At the baseline and then after 3 and 6 months

Method of measurement

Blood test

3**Description**

Low Density Lipoprotein (LDL)

Timepoint

At the baseline and then after 3 and 6 months

Method of measurement

Blood test

4**Description**

High Density Lipoprotein (HDL)

Timepoint

At the baseline and then after 3 and 6 months

Method of measurement

Blood test

5

Description

Body Mass Index (BMI)

Timepoint

At the baseline and then after 3 and 6 months

Method of measurement

Measuring weight and height and calculation of BMI

6

Description

Waist circumference

Timepoint

At the baseline and then after 3 and 6 months

Method of measurement

Direct measurement

7

Description

Fasting Blood Glucose

Timepoint

At the baseline and then after 3 and 6 months

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive standard nutritional care plus specific nutritional education (low fat, low calorie diets) for 6 months

Category

Lifestyle

2

Description

Control group will receive standard nutritional care

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Spinal Injury Research Center (BASIR)

Full name of responsible person

Street address

Imam Khomeini Hospital, Gharib Street, Keshavarz Boulevard

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Brain and Spinal Injury Research Center

Full name of responsible person

Dr. Abbas Norouzi Javidan

Street address

Reihane Building, Imam Khomeini Hospital, Gharib Street

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 Research Center

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

Brain and Spinal Injury Research Center

Full name of responsible person

Hadis Sabour

Position

Professor

Other areas of specialty/work

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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