Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of effect of Restricted Calorie diet and ad libitum diet on pain and disability in patients with chronic Sciatic pain

Protocol summary

Summary

1) Objectives: In this study we aimed to compare the effect of calorie restricted diet with ad libitum diet on pain and disability in patients with sciatic pain 2) Design: 96 patients with chronic sciatic pain who were recruited to Urmia Imam Khomeini hospital, and were candidate for nonsurgical treatment were selected. 3) Setting and conduct: Patients were divided into two groups with Simple randomization software which were equal in sex and age, one group with ad libitum diet and intervention group with 1200 calorie diet for one month. First we recorded weight of patients and then filled McGill and Roland-Morris questionnaire for them. We repeated these at 15th, 30th and 60th day. 4) Participants including major eligibility criteria: patients with chronic sciatic pain for more than 3 months, without history of spine surgery 5) Intervention: 1200k calorie diet per day for a month for intervention group 6) Main outcome measures (variables): pain severity, disability

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030316819N1**
Registration date: **2014-11-22, 1393/09/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-22, 1393/09/01

Registrant information

Name
Aisan Nozad
Name of organization / entity
Shahed University
Country
Iran (Islamic Republic of)
Phone
+98 44 3348 1143
Email address
nozad@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Without funding source

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2014-01-05, 1392/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of Restricted Calorie diet and ad libitum diet on pain and disability in patients with chronic Sciatic pain

Public title

Effect of Restricted Calorie diet in sciatic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. candidate for non-surgical treatment of sciatica pain with his treating orthopedist confirmed 2. Low back pain lasts for more than three months 3. BMI between 25 and 40 4. Age 25 to 60 years 5. constant weight (less than 6 kg of weight change during 6 months) Exclusion criteria: 1. Having other spine diseases such as kyphosis, scoliosis, spondylolisthesis 2. Having a history of spinal surgery 3. Treated with morphine or having drug addiction 4. Diabetes 5. The

current chronic physical or mental illness 6. Pregnant women 7.Lactating women 8. The history of inflammatory joint diseases such as rheumatoid arthritis and ankylosing spondylitis

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Shahed University

Street address

khalij fars highway , tehran

City

tehran

Postal code

Approval date

2013-04-10, 1392/01/21

Ethics committee reference number

41/168152

Health conditions studied

1

Description of health condition studied

Sciatic pain

ICD-10 code

M54.4 , M5

ICD-10 code description

Lumbago with sciatica , Lumbar and other intervertebral disc disorders with radiculopathy

Primary outcomes

1

Description

severity of pain

Timepoint

At beginning, 15th day, 30th day, 60th day

Method of measurement

Mc gill questionnaire

Secondary outcomes

1

Description

Disability

Timepoint

At beginning, 15th day, 30th day, 60th day

Method of measurement

Roland- Morris Questionnaire

Intervention groups

1

Description

Intervention 1: Low Calorie Diet (1200 kcal/day) for one month administered by nutrition specialist. We explained completely for patients how to manage their diet and follow them by phone.

Category

Lifestyle

2

Description

Intervention 2: continue diet without restriction for patients in control group

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini Hospital

Full name of responsible person

Aisan Nozad

Street address

Ershad Ave.

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Shahed University
Full name of responsible person
Mohsen Naseri
Street address
3d Dashtestan Ave., Shariaty Ave., Tehran
City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research, Shahed University

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
Shahed University
Full name of responsible person
Aisan Nozad
Position
Traditional Medicine PHD Candidate
Other areas of specialty/work
Street address
3rd Dashtestan Ave., Shariaty Ave., Tehran
City
Tehran
Postal code
Phone
+98 21 2288 2521
Fax
Email
aisannozad@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahed University
Full name of responsible person
Aisan Nozad
Position
Traditional Medicine PHD Candidate
Other areas of specialty/work
Street address
3rd Dashtestan Ave., Shariaty Ave., Tehran
City
Tehran
Postal code
Phone
+98 21 2288 2521
Fax
Email
aisannozad@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Full name of responsible person
Aisan Nozad
Position
Other areas of specialty/work
Street address
Tehran
City
Postal code
Phone
+98 21 2288 2521
Fax
Email
aisannozad@gmail.com , nozadaisan@yahoo.com
Web page address

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