

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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**

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**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*