

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **A study of migraine improvement after diet/exercise-induced weight loss or bariatric surgery in patients with chronic migraine who presents to Sina hospital weight-loss clinic**

#### **Protocol summary**

##### **Summary**

This study aimed to investigate the effect of smaller amounts of weight loss in different ways (surgery and diet plus exercise) on intensity, duration and frequency of migraine headaches in obese patients. Of people with migraine and overweight or obese referred to Sina hospital (Hasan Abad Avenue, TUMS, Tehran, Iran) weight loss clinic, 54 patients will be included in this clinical trial study. The characteristics of headache in 54 patients (27 in each of the bariatric surgery group or diet therapy and exercise group) with migraine and morbid obesity (BMI 35 to 93.9 range with co-morbidities or BMI > =40) for 4 weeks before surgery and at the end of the first, and sixth month of the intervention will be examined by trained physicians. In addition, a headache diary form will be fulfilled by the subjects for 4 weeks prospectively. Also, details of diet and exercise after surgery will be obtained using 3 days dietary recall and International Physical Activity Questionnaires (IPAQ) at baseline and at the end of the first and sixth months after beginning the intervention. The treatment procedure will be started after 4 weeks of baseline examination. Inclusion criteria for patients in the study were as follows having more than 15 headache days per month for at least 3 months; avoiding the use of migraine prophylactic drugs in the last 4 weeks; lack of advanced disease including kidney, heart and liver disease; the absence of major depression and psychotic disorders; suffering from morbid obesity (BMI 35 range to 39/9 with co-morbidities or BMI > =40). The exclusion criteria were as follows: lack of adherence to diet and exercise to more than 70%; pregnancy; unwillingness to cooperate in the study. The main objectives of this trial: the effect of weight loss through bariatric surgery on severity of migraine headache(using VAS), frequency and duration of migraine at one, and six months after the intervention. The effect of weight loss through diet

therapy and exercise on severity of migraine headache(using VAS), frequency and duration of migraine at one, and six months after the intervention.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT201612069157N2**

Registration date: **2016-12-26, 1395/10/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

2016-12-26, 1395/10/06

##### **Registrant information**

###### **Name**

Prof Mansoureh Togha

###### **Name of organization / entity**

Neurology department, Tehran University of Medical Sciences

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 21 6670 2052

###### **Email address**

toghae@sina.tums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

Neuroscience research center, Imam Khomeini Hospital Keshavarz Boulevard, Tehran University of Medical Sciences, Tehran, Iran

##### **Expected recruitment start date**

2016-05-02, 1395/02/13

**Expected recruitment end date**

2016-10-23, 1395/08/02

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A study of migraine improvement after diet/exercise-induced weight loss or bariatric surgery in patients with chronic migraine who presents to Sina hospital weight-loss clinic

**Public title**

The effect of weight loss (bariatric surgery or diet therapy with exercise) on migraine characteristics in obese patients with migraine headaches who referred to Sina hospital weight loss clinic

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: having more than 15 headache days per month for at least 3 months; avoiding the use of migraine prophylactic drugs in the last 4 weeks; lack of advanced disease including kidney, heart and liver disease; the absence of major depression and psychotic disorders suffering from morbid obesity (BMI 35 range to 39/9 with co-morbidities or BMI > =40). Exclusion criteria: lack of adherence to diet and exercise to more than 70%; taking Migraine prophylactic drugs; suffering from chronic kidney disease, heart and liver diseases, major depression and psychosis; pregnancy and unwillingness to cooperate in the study.

**Age**

From **18 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **54**

**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**

Tehra University of Medical Sciences

**Street address**

Tehra University of Medical Sciences, Qhods St., Keshavarz Boulevard

**City**

Tehran

**Postal code****Approval date**

2016-05-01, 1395/02/12

**Ethics committee reference number**

IR.TUMS.REC.1395.2511

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

Migraine headache

**ICD-10 code**

G43.9

**ICD-10 code description**

Migraine, unspecified

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

Migraine severity

**Timepoint**

Baseline, one month and 6 months after the intervention

**Method of measurement**

Visual Analog Scale (VAS)

**2****Description**

Migraine headache duration

**Timepoint**

Baseline, one month and 6 months after the intervention

**Method of measurement**

Migraine headache diary

**3****Description**

Migraine headache frequency

**Timepoint**

Baseline, one month and 6 months after the intervention

**Method of measurement**

Migraine headache diary

**Secondary outcomes**

## 1

### **Description**

Amount of weight reduction

### **Timepoint**

Baseline, 1 and 6 months after the intervention

### **Method of measurement**

Weight scale

## 2

### **Description**

Body fat percentage

### **Timepoint**

Baseline, 1 and 6 months after the intervention

### **Method of measurement**

BIA

## **Intervention groups**

## 1

### **Description**

Bariatric Surgery This trial will be conducted on morbid obese patients referred to Sina hospital weight loss clinic after obtaining a written consent. According to the guidelines in the treatment of obesity, bariatric surgery as a treatment is recommended in patients with morbid obesity (a body mass index of 35 to 39.9 with comorbidities or BMI >=40) . Routinely, the morbid obese patients in our obesity clinic are referred to a laparoscopic surgeon after examining their diet, physical activity and other measures as well as their willingness for bariatric surgery. headache characteristics including severity (which is obtained using VAS), frequency and duration will be determined at baseline and during the study. Also to assess dietary habits and physical activity levels of patients before surgery, three days of 24 hour dietary recall and IPAQ will be used. After surgery, low-energy diet (600-800 kcal) with 70 grams of protein and 1.8 liters of fluid per day is recommended. The dietary prescriptions for morbid obese patients who underwent surgery will be as follows: For the first day or so after surgery, and second day after the surgery: clear liquid diet, from the third day by the end of the second week: concentrated liquid, mashed and semi-solid in the third and fourth week: semi-solid diet from the end of the fourth week onward solid diet will be prescribed to patients. exercise recommendations will be given to all patients who are undergoing surgery .

### **Category**

Treatment - Surgery

## 2

### **Description**

Diet therapy and exercise obese patients who suffered from migraine and having a BMI level between 35 to 39.9 as well as morbid obese patients who are not willing to undergo for the surgery, will be treated with diet therapy and exercise. These individuals will receive 6 months of dietary prescription with exercise recommendations. diet therapy will be started by subtracting 500 to 1000 kcal

from the current energy intakes of the patient (50-55% from carbohydrates, 15-20% from protein, 30-35% from fat). The goal is achieving 30 minutes of moderate intensity physical activity per day. for achieving this goal, the patient will be asked to have a regular moderate-intensity aerobic activity for 10 minutes a day and gradually increase it to 30 minutes per day.

### **Category**

Lifestyle

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Sina hospital, weight loss clinic

#### **Full name of responsible person**

Dr Soodeh Razeghi Jahromi

#### **Street address**

Sina hospital, Hasan bad Sq, Imam Khomeini Ave, Tehran Iran

#### **City**

Tehran

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Iranian Center of Neurological Research, Tehran University of Medical Sciences,

#### **Full name of responsible person**

Mrs Zohreh Heidari

#### **Street address**

Sixth floor, Central Building of Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.

#### **City**

Tehran

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Iranian Center of Neurological Research, Tehran University of Medical Sciences,

### **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**

Iranian Center of Neurological Research, Tehran  
University of Medical Sciences

**Full name of responsible person**

Prof. Mansoureh Togha

**Position**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work****Street address**

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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*