Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of Topiramate on weight loss in Iranian patients with diabetes type 2

Protocol summary

Summary

Obesity is a complex disease that represents a growing epidemic worldwide. Obesity is no longer a cosmetic issue; it has been found to be associated with several co morbidities and increased mortality. In general, the use of medication promotes only a modest weight loss, in the range of 2 to 10kg. The effects are generally maximal during the first 6 months of therapy. The aim of this study was to assess the effect of Topiramate on weight reduction in a group of obese diabetic patients. In this study, 85 subjects were included. Patients were assigned in two treatment groups with Topiramate and Placebo. All subjects participated in a non-pharmacologic lifestyle intervention program. Primary efficacy end points were percent change in body weight at the end of the study. Secondary end points were change in blood pressure(BP), proportion of subjects who achieved 5% or 10% weight loss, changes in lipid profile (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides) ; and changes in glycosylated hemoglobin (HgA1c).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112036027N2**
Registration date: **2012-02-18, 1390/11/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-18, 1390/11/29

Registrant information

Name

Sedigheh Moradi

Name of organization / entity

Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 5247

Email address

s-moradi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-10-01, 1387/07/10

Expected recruitment end date

2010-01-01, 1388/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Topiramate on weight loss in Iranian patients with diabetes type 2

Public title

The effect of Topiramate on weight loss in Iranian patients with diabetes type 2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- patients aged 18–75 years 2-body mass index (BMI) between 27 and 50 kg/m2 3-documented history of type 2 diabetes mellitus 4-glycosylated hemoglobin (HbA1c) less than 11% 5- blood pressure (BP) less than 160/105 mmHg 6-constant weight for at least 3 months (±3 kg). Exclusion criteria: 1-History of central nervous system (CNS) related or

psychiatric disorders 2-Significant renal, hepatic or thyroid disease 3- Pregnancy 4- Sever diabetes complications

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

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
Tehran University of Medical Sciences

Street address
Keshavarz BLV, Qods st, Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2008-08-20, 1387/05/30

Ethics committee reference number
501

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66.9

ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Percent change in body weight

Timepoint
End of the study

Method of measurement
Body mass index measurment

Secondary outcomes

1

Description
Change in systolic and Diastolic blood pressure

Timepoint
At the end of study

Method of measurement
Blood pressure measurment

2

Description
Changes in glycosylated hemoglobin (HgA1c)

Timepoint
At the end of study

Method of measurement
HbA1C measurment

3

Description
Changes in lipid profile (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides)

Timepoint
At the end of study

Method of measurement
Lipid profile measurment

4

Description
Proportion of subjects who achieved 5% or 10% weight loss (5% and 10% weight responders)

Timepoint
At the end of study

Method of measurement
weight measurment with standadrd method

Intervention groups

1

Description
Intervention: The 3-week titration phase began with administration of 25mg topiramate once every morning to subjects assigned to that group. In the second week, topiramate was administered at 25mg twice daily (50 mg/day). The dose was thereafter increased to 100 mg/day (50 mg in the morning and 50 mg in the evening). The maintenance phase began in the 4th week with the dose of 150mg/day. Finally the dose was

tapered to 75 mg/day in the first week and 25mg/day in the second week up to either completion of or early withdrawal from the study.

Category

Treatment - Drugs

2

Description

Control:The 3-week titration phase began with administration of 25mg placebo tablet(prduced by Arya pharmacy company) that had shape and cover similar to topiramate tablets once every morning to subjects assigned to this group. In the second week, placebo tablet was administered at 25mg twice daily (50 mg/day). The dose was thereafter increased to 100 mg/day (50 mg in the morning and 50 mg in the evening). The maintenance phase began in the 4th week with the dose of 150mg/day. During the maintenance phase, the dose remained constant . Finally the dose was tapered to 75 mg/day in the first week and 25mg/day in the second week up to either completion of or early withdrawal from the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and metabolism Research center, Firouzgar hospital

Full name of responsible person

Sedighe Moradi

Street address

Endocrine and metabolism Research center, Firouzgar hospital,Valiasr sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Roghayeh Malmir

Street address

Keshavarz BLv, Qods st, Tehran University of Medical sciences, 5th floor, Research Unit

City

Tehran

Grant name

م-ت

Grant code / Reference number

131م-ت

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

Yes

Title of funding source

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

Tehran University of Medical Sciences

Full name of responsible person

Sedighe Moradi

Position

Assistant professor

Other areas of specialty/work

Street address

Endocrine and metabolism Research center, Firouzgar hospital,Valiasr sq.

City

Tehran

Postal code

Phone

+98 21 2620 2448

Fax

Email

s-moradi@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sedighe Moradi

Position

Assistant professor

Other areas of specialty/work

Street address

Endocrine and metabolism Research center, Firouzgar hospital,Valiasr sq.

City

Tehran

Postal code

Phone

+98 21 2620 2448

Fax

Email

s-moradi@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Sedighe Moradi

Position
Assistant professor

Other areas of specialty/work

Street address
Endocrine and metabolism Research center, Firouzgar hospital,Valiasr sq.

City
Tehran

Postal code

Phone

Fax

Email

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