

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

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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- Severe 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 measurement

Secondary outcomes

1

Description

Change in systolic and Diastolic blood pressure

Timepoint

At the end of study

Method of measurement

Blood pressure measurement

2

Description

Changes in glycosylated hemoglobin (HgA1c)

Timepoint

At the end of study

Method of measurement

HbA1C measurement

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 measurement

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 measurement with standard 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 (produced 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.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical sciences

Full name of responsible person

Roghayeh Malmir

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City

Tehran

Grant name

م-ت

Grant code / Reference number

م-ت 131

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

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Position

Assistant professor

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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