

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Aug 2026

Compare the Efficacy of Bupropion tablets with sildenafil tablet and Ginseng in sexual function in men with type 2 diabetes with erectile dysfunction.

Protocol summary

Summary

In the present double-blind clinical trial study, 80 men suffering from type 2 diabetes and sexual dysfunction who refer to the endocrinology clinic of Valiasr Hospital of Zanjan are recruited. For all patients sexual dysfunction standard questionnaires will be completed; personal demographics, anthropometric measurements, and drug history will be also taken. Then they are randomly assigned to four twenty-member groups including: sildenafil, bupropion, Ginseng, and placebo. For 10 weeks, patients of four groups are treated with oral medication including 50 mg of sildenafil tablet to the first group, 150 mg of bupropion (extended release) to the second group, Ginseng to the third group, and placebo to the forth group. After 10 weeks, for all the participants the questionnaires will be completed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111819554N11**
Registration date: **2016-12-11, 1395/09/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-11, 1395/09/21

Registrant information

Name

Maryam Jameshorani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the Efficacy of Bupropion tablets with sildenafil tablet and Ginseng in sexual function in men with type 2 diabetes with erectile dysfunction.

Public title

Effect of bupropion tablets compared to sildenafil tablets and Ginseng on sexual function (erectile dysfunction) in men with type 2 diabetes who were referred to endocrinology clinic of Vali Asr Hospital of Zanjan.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 30-80 years old; sexual dysfunction from 6 month ago; no relationship problems with partner from 6 month ago; HbA1c less than 10 & FBS less than 200 from 6 month ago; normal serum testosterone and prolactin levels; non-interference in

the our drugs with prescription medications; no history of priapism. Exclusion criteria: the anatomical penile dysfunction; history of prostatectomy; sever hematologic & renal &liver dysfunction; Nitrate consumption; coronary artery disease; blood pressure more than 170/100 or less than 90, proliferative retinopathy; autonomic neuropathy; ketoacidosis history in 2 years ago; tachycardia.

Age

From **30 years** old to **80 years** old

Gender

Male

Phase

2-3

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**

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Jomhoori
Eslami street, Azadi blv

City

Zanjan

Postal code

45156-13191

Approval date

2015-04-29, 1394/02/09

Ethics committee reference number

IR.ZUMS.REC.1394.01

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

N52.9

ICD-10 code description

Male erectile dysfunction, unspecified

Primary outcomes

1

Description

erectile dysfunctions

Timepoint

first day and 10 weeks later

Method of measurement

IIEF-5 standard questionnaire

2

Description

serum colestrol level

Timepoint

first day

Method of measurement

laboratory kits (Calorimetry enzymatic)

3

Description

serum triglyceride level

Timepoint

first day

Method of measurement

laboratory kits (Calorimetry enzymatic)

4

Description

serumfasting blood sugar level

Timepoint

first day

Method of measurement

laboratory kits (Calorimetry enzymatic)

5

Description

HbA1c

Timepoint

first day

Method of measurement

laboratory kits

6

Description

serum prolactin level

Timepoint

first day

Method of measurement

laboratory kits (elisa)

7

Description

serum Testosterone level

Timepoint

first day

Method of measurement

laboratory kits (elisa)

Secondary outcomes

empty

Intervention groups**1****Description**

20 patients: Bupropion Tab(150mg)for 10 weeks

Category

Treatment - Drugs

2**Description**

20 patients: Sildenafil Tab(50mg)for 10 weeks.

Category

Treatment - Drugs

3**Description**

20 patients: Ginseng capsule for 10 weeks

Category

Treatment - Other

4**Description**

20 patients: placebo for 10 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endocrinology Clinic,Valiasr Hospital

Full name of responsible person

Dr. Ahmad Zolghadriha

Street address

Valiasr Hospital,Valiasr square

City

Zanjan

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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Zanjan University of Medical Sciences, Jomhoori
Eslami street, Azadi blvd.

City

Zanjan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Maryam Jameshorani

Position

Internist

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

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Position

Psychiatrist

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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