Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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: sindenafil, bupropion, Ginseng, and placebo. For 10 weeks, patients of four groups are treated with oral medication including 50 mg of sindenafil 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
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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 ild; 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 prolactine 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 enzimatic)

3

Description
serum triglyceride level

Timepoint
first day

Method of measurement
laboratory kits (Calorimetry enzimatic)

4

Description
serumfasting blood sugar level

Timepoint
first day

Method of measurement
laboratory kits (Calorimetry enzimatic)

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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