

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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 fourth 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

00989126416972 00982433770805

##### Email address

dr.shirinjameshorani@zumc.ac.ir

##### 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

**Street address**

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**

Valiasr Hhospital, Valiasr square

**City**

Zanjan

**Postal code**

45157-77978

**Phone**

+98 24 3377 0814

**Fax****Email**

dr.shirinameshorani@yahoo.com

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Abolfazl Gghoreishi

**Position**

Psychiatrist

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

Beheshti Hospital, Ark square

**City**

Zanjan

**Postal code**  
4513815788  
**Phone**  
+98 24 3354 4000  
**Fax**  
**Email**  
sabgho@zums.ac.ir  
**Web page address**

4513815778  
**Phone**  
+98 24 3354 4000  
**Fax**  
**Email**  
ahmad\_zolghadriha@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Dr. Ahmad Zolghadriha  
**Position**  
Resident of Psychiatry  
**Other areas of specialty/work**  
**Street address**  
Beheshti Hospital, Ark square  
**City**  
Zanjan  
**Postal code**

## 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*