

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The assessment of efficacy of folic acid plus tadalafil in treatment of erectile dysfunction in men with diabetes mellitus type II

Protocol summary

Summary

Erectile dysfunction is one the common problems of sexual function in men with more prevalence in diabetic men. In our study that is a randomized controlled clinical trial (RCT), 100 men aged 40 to 70 years with diabetes mellitus who suffered from moderate to severe erectile dysfunction were studied in two groups (A and B) with "random fixed block" method. In group A, patients were undergoing with 10 mg tadalafil every other day and 5 mg folic acid daily. In group B, as a control, cases were undergoing with 10 mg tadalafil every other day and placebo. The data were recorded before and after treatment with the IIEF questionnaire and then compared between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009054582N3**

Registration date: **2010-10-14, 1389/07/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-14, 1389/07/22

Registrant information

Name

Ali Hamidi Madani

Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1552 5259

Email address

hamidimadani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center of Guilan University of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of efficacy of folic acid plus tadalafil in treatment of erectile dysfunction in men with diabetes mellitus type II

Public title

Efficacy of folic acid in treatment of erectile dysfunction in men with diabetes mellitus type II

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- moderate to server Erectile Dysfunction at least 3 months (IIEF < 17). 2- Diabetes mellitus type II. 3- No history of folic acid in last 3 months. Exclusion criteria: 1- Erectile dysfunction with known psychological origin. 2- Cord injury. 3- Patients who are under treatment with folic acid. 4- Contraindication of consumption of 5-phosphodiesterase inhibitors for example history of anaphylactic reaction. 5- Hypertension. 6- Antihypertensive and antilibido drugs consumption. 7- Hyperthyroidism.

Age

From **40 years** old to **70 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Assistant of Guilan University of Medical Sciences

Street address

The Research Assistant of Guilan University of Medical Sciences

City

Rasht

Postal code

Approval date

2010-08-07, 1389/05/16

Ethics committee reference number

3073

Health conditions studied

1

Description of health condition studied

Erectile Dysfunction

ICD-10 code

N40-N51

ICD-10 code description

Diseases of male genital organs

Primary outcomes

1

Description

Improvement of rectile function

Timepoint

3 months

Method of measurement

IIEF questionnaire (International Index of Erectile Function)

Secondary outcomes

empty

Intervention groups

1

Description

Placebo tablet, once daily for 3 months

Category

Placebo

2

Description

Acid folic tablet (5 mg), once daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology Clinic of Razi Hospital

Full name of responsible person

Dr. Ahmad Asadollahzadeh

Street address

Razi Hospital

City

Rasht

2

Recruitment center

Name of recruitment center

Dr. Ali Hamidi Madani's Clinic

Full name of responsible person

Dr. Ali Hamidi Madani

Street address

Dr. Ali Hamidi Madani's Clinic

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology Research Center

Full name of responsible person

Dr. Siavash Falahatkar, Manager of Urology Research Center

Street address

Urology Research Center, Razi Hospital

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urology Research Center

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

Urology Research Center

Full name of responsible person

Dr. Ahmad Asadollahzadeh

Position

Coworker/Resident of Urology

Other areas of specialty/work

Street address

Urology Research Center, Razi Hospital

City

Rasht

Postal code

4144895655

Phone

+98 13 1552 5259

Fax

+98 13 1552 5259

Email

asad2418@yahoo.com ; urc1384@yahoo.com

Web page address

www.urc.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urology Research Center

Full name of responsible person

Dr. Ali Hamidi Madani

Position

Assistant Prof.

Other areas of specialty/work

Street address

Urology Research Center, Razi Hospital

City

Rasht

Postal code

4144895655

Phone

+98 13 1552 5259

Fax

+98 13 1552 5259

Email

a42hamidi2000@yahoo.com ; urc1384@yahoo.com

Web page address

www.urc.ir

Person responsible for updating data

Contact

Name of organization / entity

Urology Research Center

Full name of responsible person

Samaneh Esmaeili

Position

Urology Research Center secreter/ Bachlor

Other areas of specialty/work

Street address

Urology Research Cente, Razi Hospital

City

Rasht

Postal code

4144895655

Phone

+98 13 1552 5259

Fax

+98 13 1552 5259

Email

samaneh_815@yahoo.com ; urc1384@yahoo.com

Web page address

www.urc.ir

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