

# 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**

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Position**

Assistant Prof.

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Urology Research Center

**Full name of responsible person**

Samaneh Esmaeili

**Position**

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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*