

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of Tadalafil , Toltrodine and Placebo in reduction of symptoms severity of women with Urgency,frequency syndrom / Overactive bladder

Protocol summary

Summary

The main objective of our study is to investigate of efficacy of Tadalafil in reduction of symptoms severity of women that suffering from Overactive bladder syndrome. Method is triple blind randomized clinical trial. The study population is premenopausal women age ranged between 18 to 50 years old that referred to Female Urology Clinic of Tabriz University of Medical Sciences with first presentation of urgency with or without incontinence. Exclusion criteria included of urine culture positive, abnormal ultrasonography, diabetes, any identified neurologic disorders and previous medical therapy. After explaining the research objectives of the study and informed consent, patients will be enrolled. The study will be conducted with a sample size of 90 subjects. The main interventions include the use of oral tadalafil tablets and two control groups by Tolterodine and Placebo are involved. Data collection is ICIQ-OAB questionnaire that validated in Persian. Symptoms severity of patients before and after four weeks of treatment is measured by the questionnaire. Reduction in symptoms severity after 4 weeks of treatment is considered as the primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013030212668N1**
Registration date: **2013-05-21, 1392/02/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-21, 1392/02/31

Registrant information

Name

Reza Sari motlagh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1545 1054

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Tadalafil , Toltrodine and Placebo in reduction of symptoms severity of women with Urgency,frequency syndrom / Overactive bladder

Public title

Effect of Tadalafil in treatment of Overactive bladder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female with urgency with or without urge incontinence; First presentation of disease;

Nonmenopause; Age range between 18 and 50 years old.
Exclusion criteria: Previous medication therapy;
Abnormal ultrasonography of kidneys, ureters and bladder; Positive urine culture; Diabetes; Identified urologic disorders; Age less than 18 years old; Age greater than 50 years old; Menopause.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht st. ,
Tabriz

City

Tabriz

Postal code

Approval date

2013-01-26, 1391/11/07

Ethics committee reference number

91189

Health conditions studied

1

Description of health condition studied

overactive bladder syndrome

ICD-10 code

N32.8

ICD-10 code description

Bladder contracted

Primary outcomes

1

Description

Reduction of the symptoms severity

Timepoint

Before and 4 weeks after treatment

Method of measurement

ICIQ-OAB questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Tolterodine, Tab. 2 mg Oral, q12h for 4 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Tadalafil, Tab. 20 mg Oral, qod for 4 weeks

Category

Treatment - Drugs

3

Description

Control group: Placebo(glucose), Tab. 1 Number Oral, qod for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Female Urology Clinic of Emam reza Hospital related to Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Hajebrahimi

Street address

Female Urology Clinic, Emam reza Hospital, Golgasht st. , Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Research of Medical School of Tabriz University
of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Vice-research of Medical School of Tabriz University of
Medical Sciences, Golgasht st. , Tabriz

City

Tabriz

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

Yes

Title of funding source

Vice-Research of Medical School of Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Reza Sari motlagh

Position

Resident of Urology

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

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Sakineh Hajebrahimi

Position

Subspecialist of Female Urology and Urodynamic

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Fax**Email****Web page address****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