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
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Iran (Islamic Republic of)
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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;

Nonmenpause; Age range between 18 and 50 years old. Exclusion criteria: Previous medication therapy; Abnormal ultrasonography of kidneys,ureters and bladder; Positive urine cultur; Diabetes; Identified norologic 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 syndrom

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
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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