Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The Comparison Between Traditional Iranian Medicine Product Consist of "Myrtus Communis" with "Toltrodine" in Control of Urge Urinary Incontinence in Women

Protocol summary

Summary

1) Objectives: Investigate the efficacy of an Iranian Traditional Medicine product consist of "Myrtus Communis" with "Toltrodine" in control of urge urinary incontinence in women. 2) Method : Randomized clinical trial. 3) The study population: Major inclusion criteria: 18-80 old women with urge or mixed with urge dominance urinary incontinence who referred to pelvic floor clinic in Imam Khomeini Hospital of Tehran. Other inclusion criteria: Been symptomatic from at least 3 months ago; not have been treated for at least 2 week before study; Who are health mentally and physically. Exclusion criteria: Positive urine culture; Uncontrolled diabetic; Uncontrolled HTN; History of glaucoma; History of drug allergy; Neuralgic disease; Bladder cancer; Hematuria; Residual volume more than 110 in sonography; Any voiding dysfunction in history. 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 72 subjects. Interventions: "Toltrodine" is given to control group and herbal medicine syrup consist of "Myrtus Communis" is given to case group. Duration of intervention: 4 weeks. Major out come variations: Reduction in symptoms severity after treatment upon ICIQ-SF questionnaire that is validated in Persian.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102819734N1**
Registration date: **2015-01-13, 1393/10/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-13, 1393/10/23

Registrant information

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Recruitment status

Recruitment complete

Funding source
Vice Chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison Between Traditional Iranian Medicine Product Consist of "Myrtus Communis" with "Toltrodine" in Control of Urge Urinary Incontinence in Women

Public title

Efficacy of Traditional Iranian Medicine Product in Control of Urinary Incontinence in Women

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Female with urge incontinence or mixed incontinence with urge dominance; Who have been symptomatic from at least 3 months ago; Not have been treated for at least 2 week; and are health mentally. Exclusion criteria: Positive urine culture; Uncontrolled diabetic; Uncontrolled HTN; History of glaucoma; History of drug allergy; Neuralgic disease; Bladder cancer; Hematuria; Residual volume more than 110 in sonography; Any voiding dysfunction in history
Age
From **18 years** old to **80 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Science
Street address
501, 5th Floor, Central Building of Tehran University of Medical Sciences, Keshavarz and Qods Junction, Tehran, Iran
City
Tehran
Postal code
Approval date
2013-08-21, 1392/05/30
Ethics committee reference number
92/5/130/1058

Health conditions studied

1

Description of health condition studied
urge urinary incontinence
ICD-10 code
N39.4
ICD-10 code description
Other specified urinary incontinence

Primary outcomes

1

Description
Reduction of the symptoms severity
Timepoint
Before and 4 weeks after treatment
Method of measurement
ICIQ-SF questionnaire

Secondary outcomes

1

Description
advers effect of drug
Timepoint
any time after starting drug
Method of measurement
asking from patients

Intervention groups

1

Description
Intervention group: Traditional Herbal Syrup which is a aqueous extract of "Myrtus Communis" leaves. Dosage: 15 cc 20-40 min after each meal means 45 cc per day.
Category
Treatment - Drugs

2

Description
Control group: Tab 2 mg "Toltrodine" 2 times a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pelvic Floor Clinic of Imam Khomeini Hospital belongs to Tehran University of Medical Science
Full name of responsible person
Fatemeh Nojavan
Street address
End of Keshavarz Blv, Tehran, Iran
City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Iran University of Medical Sciences
Full name of responsible person
Dr Morteza Naserbakht
Street address
Hemmat Hwy, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Iran 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

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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