

# 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

###### Name

Fatemeh Nojavan

###### Name of organization / entity

Iran University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3316 8839

###### Email address

nojavan.f@tak.iums.ac.ir

##### 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 "Toltridine" 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

## 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

**City**

Tehran

**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

#### Contact

**Name of organization / entity**

Research Institute for Islamic and Complementary Medicine

**Full name of responsible person**

Fatemeh Nojavan

**Position**

Ph.D Student of Traditional Iranian Medicine

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

No. 9, Pirnia alley, Lalezar Now Ave., Jomhour Eslami St., Tehran

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Zinat Ghanbari

**Position**

Specialist of Obstetric and Gynecology

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

End of Keshavarz Blv, Imam Khomeini Hospital, Pelvic Floor Clinic, Tehran, Iran

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## Person responsible for updating data

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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*