

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparative study of the efficacy of solifenacin with duloxetine in the treatment of overactive bladder disease in women

Protocol summary

Study aim

comparision of the efficacy of solifenazine with doloxetine in the treatment of overactive bladder in women referred to Besat clinic of kerman

Design

Clinical trial, with parallel groups, single blind, No randomization

Settings and conduct

Overactive bladder disease status and drug side effects that the evaluator does not know the type of drug the population of the study is women referring to Kerman Beatitudes Clinic with urinary frequency more than 5-6 times per day at less than 1 hour intervals

Participants/Inclusion and exclusion criteria

Inclusion criteria are: All women had urinary frequency more than six times a day at intervals less than one hour
Exclusion criteria are: urinary tract infection, diabetes, under 18 years old, BMI greater than 35, smokers, having bladder stones , pervious surgical history

Intervention groups

Intervention group: anti-cholinergic drug name is Soli-phenazine 10 mg daily for 4 week
Control group: Serotonin reuptake inhibitor norepinephrine duloxetine 20 mg daily for 4 week

Main outcome variables

Bladder disease status and drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191010045047N1**
Registration date: **2019-12-19, 1398/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

salar dozchizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3626 6165

Email address

salar dozchizade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-17, 1398/07/25

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the efficacy of solifenacin with duloxetine in the treatment of overactive bladder disease in women

Public title

Comparison of the efficacy of solifenacin and duloxetine in the treatment of overactive bladder disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All women had urinary frequency more than six times a

day at intervals less than one hour

Exclusion criteria:

urinary tract infection diabetes under 18 years old BMI greater than 35 smokers having bladder stones previous surgical history

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study was a single-blind clinical trial study
The evaluator does not know the type of drug

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kerman medical university

Street address

Emam highway paradise afzalipoor the afzalipoor hospital

City

kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۹۱۱

Approval date

2019-09-30, 1398/07/08

Ethics committee reference number

IR.KMU.AH.REC.1398.099

Health conditions studied

1

Description of health condition studied

over active bladder

ICD-10 code

N32.81

ICD-10 code description

other specified disorders of bladder

Primary outcomes

1

Description

Patients symptoms of OAB

Timepoint

First of trial and one month later

Method of measurement

International consultation on incontinence questionnaire

2

Description

Drug side effects

Timepoint

One month later

Method of measurement

Patient history

Secondary outcomes

empty

Intervention groups

1

Description

intervention Group 1: 10mg daily anti-cholinergic solifenacin drug made by abidi Pharmaceutical Company for a month

Category

Treatment - Drugs

2

Description

Intervention group2: Serotonin norepinephrine reuptake inhibitor Duloxetine 20 mg daily by abidi Pharmaceutical Company for a month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beast clinic

Full name of responsible person

Mahbobe mirzaei

Street address

Somayeh intersection (Tahmasb Abad), next to the old Kerman hospital

City

kerman
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas pardakhti
Street address
isar blvd,yaghot2,plaque13
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Grant name
0
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mahbobe mirzaei
Position
Assistant Professor
Latest degree
Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available