

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy and tolerability of pediatric primary enuresis treatment with Solifenacin and Tolterodine in children

Protocol summary

Study aim

Comparison of efficacy and tolerability of solifenacin and tolterodine in the treatment of primary enuresis in children. comparing the average number of enuresis in the month before the intervention, one month, and three months after the intervention in children. comparing the frequency of complete recovery after 3 months of treatment in children. comparing the frequency of drug side effects in children. comparing the average satisfaction at the end of three months of treatment in children.

Design

A clinical trial with parallel, blind, randomized, phase 3 groups will be performed on 66 patients and permutation blocks will be used for randomization.

Settings and conduct

This research will be conducted in the urology clinic of Ali Bin Abi Talib Zahedan Hospital. This clinical trial study with the participation of 66 children with primary nocturnal enuresis (in two groups of 33 people) will be treated with solifenacin and tolterodine drugs, and the patient's recovery, satisfaction with the treatment, and its side effects will be evaluated.

Participants/Inclusion and exclusion criteria

The study population: children with primary enuresis who referred to the urology clinic of Ali Ibn Abi Talib Hospital in Zahedan, Iran in 2022. Inclusion criteria: Patient availability during follow-up and Age 5 to 14 years. exclusion criteria: Structural disorders of the urinary tract; Neurological bladder; Psychiatric diseases; Previous allergy to drugs and History of taking medication (drug therapy) for enuresis and Urinary incontinence.

Intervention groups

1- children who will be treated with tolterodine 2 mg per night, made by Daru Pakhsh Company, Iran. 2- children who will be treated with solifenacin 5 mg per night, made by Caspian Daru Company, Iran.

Main outcome variables

Number of enuresis, satisfaction with treatment, expected complications, complete recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220520054929N1**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **prospective**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

Registration date

2022-09-05, 1401/06/14

Registrant information

Name

fateme Ghaderi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3337 2151

Email address

fatemeh.ghaderi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-16, 1401/06/25

Expected recruitment end date

2022-12-16, 1401/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and tolerability of pediatric primary enuresis treatment with Solifenacin and Tolterodine in children

Public title

Evaluation of the effect of sulifenacin and tolterodine in the treatment of primary enuresis in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with primary enuresis referred to the clinic of Ali Bin Abi Talib Hospital in Zahedan
Consent to study
Patient availability during quarterly follow-up
Age 5 to 14 years

Exclusion criteria:

Structural disorders of the urinary tract
Neurological bladder
Psychiatric diseases
Previous allergy to drugs
History of taking medication (drug therapy) for enuresis
Urinary incontinence

Age

From **5 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this study will be available based on the entry and exit criteria, and the random allocation of patients to two groups will be done with the permuted block stratified randomization method. In this way, first, eligible referring patients are classified according to age and gender in the order of entry. Then they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations. These blocks were created using statistical software R version 4.0.2.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will enter the study after completing the informed consent and explaining the content of the study. The blinding process will be as follows: Patients will be treated with prescription packages pre-determined by the study supervisor (supervisor). Drug

packages are quite similar in shape and the project manager is not aware of the contents of the packages. In addition, information collection, patient assessment and completion of forms is done by the project manager and his assistant who are not aware of the contents of the packages; In the data analysis stage, the analysis will be performed by the project consultant and the project manager who are not aware of the contents of the drug packages and only the group of patients (group 1 or 2) will be determined to analyze the data; Therefore, the study is three-blind and the contents of the two drug groups are not clear from the stage of the patient entering the study to perform the study, data collection and data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Zahedan University Of Medical Sciences

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ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

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Postal code

9816743463

Approval date

2022-05-15, 1401/02/25

Ethics committee reference number

IR.ZAUMS.REC.1401.060

Health conditions studied**1****Description of health condition studied**

pediatric primary enuresis

ICD-10 code

N39.44

ICD-10 code description

Nocturnal enuresis

Primary outcomes

1

Description

enuresis status (number of times)

Timepoint

Before the intervention, one month and three months after the intervention

Method of measurement

Number of enuresis nights during 1 month

2

Description

Full recovery

Timepoint

3 months after the intervention

Method of measurement

Based on the patient's history

3

Description

Complications during the intervention

Timepoint

During the 3 months of intervention

Method of measurement

Based on the patient's history

4

Description

Satisfaction with treatment

Timepoint

3 months after the intervention

Method of measurement

Based on the 5-point criterion after taking the drug

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Solifenacin treated group (this group will be treated with Solifenacin 5 mg every night, manufactured by Caspin Daru Company, Rasht, Iran for 3 months. Then the patients were visited at the end of the first and third month and the amount Nocturnal enuresis, incidence of side effects (in the solifenacin group included dry mouth, constipation, abdominal pain and nausea) will be evaluated.

Category

Treatment - Drugs

2

Description

Intervention group 2: Tolterodine treated group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Bin Abitalib Hospital Zahedan

Full name of responsible person

Saeed Movahed

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Persian Gulf Highway, Salamat Blvd., Zahedan City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad Reza Shahraki

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Ghaderi

Position

پزشک عمومی

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

Fateme Ghaderi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the studied data (without identity information) will be obtained.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions related to medical sciences

Under which criteria data/document could be used

The data will be placed in the form of all valid people (ensuring that the people are researchers).

From where data/document is obtainable

Fateme Ghaderi (responsible for updating the study), contact: fatemeh.ghaderi@zaums.ac.ir

What processes are involved for a request to access data/document

Please send your request to the attached email. The data will be available to the applicants 6 months after the publication of the results in the publishers. (The data will be served to people within a week after the request).

Comments