Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 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)

Phone

+98 54 3337 2151

Email address

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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 Conscious 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

Street address
ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

City
Zahedan

Province
Sistan-va-Balouchestan

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
Street address
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
Street address
Salamat Blvd., Persian Gulf Highway, Zahedan City
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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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Full name of responsible person

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Position

Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fateme Ghaderi

Position

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Other areas of specialty/work

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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

Fatemeh 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