Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Recurrence of primary enuresis after treatment with desmopressin compare with combination therapy desmopressin and tolterodine in children aged 5-16 years

Protocol summary

Study aim

Determination of primary nocturnal enuresis recurrence in Desmopressin treatment compared to combination therapy of Desmopressin and Toltrudin in children 5-16 years old.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 124 patients. Patients will be randomly divided into two groups by random allocation with permuted blocks then order selected with random numbers generated by the computer. The therapist and the patient will be unaware of the treatment allocation.

Settings and conduct

Nephrology clinic of Qods hospital in Qazvin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with primary monosymptomatic enuresis; No underlying disease or any anatomical abnormalities of the kidney on ultrasound; Age 5 to 16 years; Have informed consent to participate or withdraw from the study; nocturnal enuresis at least three nights a week. Exclusion criteria: Patients with nocturnal enuresis with daily urinary disorder symptoms, such as emergency urinary incontinence, frequent urination or reduced frequency of urine per day, everyday urination holding maneuvers; Patients with urinary tract infection (positive urine culture), fasting blood sugar, kidney dysfunction (high creatinine), anatomical disorders of kidney in ultrasonography.

Intervention groups

The intervention group receives Desmopressin, and Toltrudin and the control group receives Desmopressin and placebo.

Main outcome variables

Early enuresis recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210714051893N1**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **prospective**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Fereshteh Sobhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8849 5179

Email address

fereshteh.sobhani23@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Recurrence of primary enuresis after treatment with desmopressin compare with combination therapy desmopressin and tolterodine in children aged 5-16 years

Public title
"Combination therapy in recurrence of enuresis"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients have monosymptomatic primary enuresis. Patients without any anatomical disorder of kidney in sonography Patients aged 5 -16 years Knowledgeably compliance for entry or exit from research

Exclusion criteria:
Patients with enuresis with symptoms of daily urinary disorders, such as urgent urinary incontinence, frequent urination, or reduced urination frequency per day, urinary retention maneuvers during the day. Patients with urinary tract infection (positive urine culture), fasting blood sugar, renal dysfunction (high creatinine), Anatomical abnormalities of the kidney on ultrasound, patients previously treated for enuresis patients with incomplete information, and no referrals if the child does not have enuresis (has gained control of urination) and later has enuresis secondary enuresis

Age
From **5 years** old to **16 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups. (By random allocation method with variable blocks that creates six different states (TCCT). TCTC TTCC. CTTC. CTCT. CCTT). Then the order will be selected by random numbers created by the computer). The therapist and the patient do not know about the group allocation. In addition, the Quickcals graphpad program is used for randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Double-blind, Patients and the therapist are not aware of the type of allocation. For this purpose, the drugs are divided into packages containing codes 1 or 2. Only the principal investigator is aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Qods hospital,Qods square

City
Qazvin

Province
Qazvin

Postal code
3415914595

Approval date
2021-06-23, 1400/04/02

Ethics committee reference number
IR.QUMS.REC.1400.138

Health conditions studied

1

Description of health condition studied
Primary monocympetic nocturnal enuresis

ICD-10 code
N39.44

ICD-10 code description
Nacturnal enuresis

Primary outcomes

1

Description
Nocturnal enuresis

Timepoint
After starting treatment, patients will be visited monthly. If there is a partial or no response up to two weeks after treatment, possible factors of resistance to treatment such as constipation, bladder disorders or not taking the drug properly will be investigated. Failure to respond to treatment refers to one or more night wetting in two consecutive weeks during treatment and response to treatment is defined as dryness in two consecutive weeks.After three months of treatment, the drugs are discontinued overnight for one month. Re-visits are performed two weeks after treatment and recurrence of nocturnal enuresis (more than three nights wetting per week) will be checked.

Method of measurement
Response to treatment questionnaire.

Secondary outcomes

1

Description
Early enuresis recurrence
Timepoint
En After starting treatment, patients will be visited monthly. If there is a partial or no response up to two weeks after treatment, possible factors of resistance to treatment such as constipation, bladder disorders or not taking the drug properly will be investigated. Failure to respond to treatment refers to one or more night wetting in two consecutive weeks during treatment and response to treatment is defined as dryness in two consecutive weeks.After three months of treatment, the drugs are discontinued overnight for one month. Re-visits are performed two weeks after treatment and recurrence of nocturnal enuresis (more than three nights wetting per week) will be checked.
Method of measurement
En Response to treatment questionnaire.

Intervention groups

1

Description
Control group: Patients will be randomly divided into two groups: (CCTT) by random allocation with variable blocks that create six different states. CTCT. CTTC. TTCC TCTC. (TCCT) and then the blocks are selected with random numbers generated by the computer. The therapist and the patient are not aware of the therapeutic allocation. The first group is given 10 micrograms of Desmopressin nasal spray (one puff) one hour before bedtime and patients will be visited after the start of monthly treatment.If there is a partial or no response within two weeks of treatment, possible factors for resistance to treatment, such as constipation, bladder disorders, or improper medication, are evaluated. Failure to respond to treatment to one or more overnight wetting for two consecutive weeks during treatment and response to treatment refers to being dry for two consecutive weeks (provided the medication is used continuously). Night in between and then cut off.Re-visit two weeks after treatment and recurrence of enuresis (wetting more than three nights a week) will be checked. It is used as an active ingredient and each puff contains 10 micrograms of desmopressin acetate. The following recommendations will be made to patients in both groups.1. Adequate fluid intake during the day by limiting fluids to two hours before bedtime 2. Do not drink caffeinated beverages in the afternoon and evening 3. Empty the bladder before bedtime.
Category
Treatment - Drugs

2

Description
Intervention group: The second group given 10 microgram of Desmopressin nasal spray (one puff)with Tolterodine tablets (1/2 of tablet)(Sanamad Pharmaceutical Company) one hour before bedtime. will also be prescribed to the second group of patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qods hospital
Full name of responsible person
Fereshteh Sobhani
Street address
Qods hospital,Qods square
City
Qazvin
Province
Qazvin
Postal code
3415914595
Phone
+98 28 3333 4807
Email
fereshteh.sobhani23@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fereshteh Sobhani
Street address
Qods hospital,Qods square
City
Qazvin
Province
Qazvin
Postal code
3415914595
Phone
+98 28 3333 4807
Email
fereshteh.sobhani23@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Fereshteh Sobhani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Qods hospital,Qods square

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3333 4807

Email

fereshteh.sobhani23@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Fereshteh Sobhani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Qodshospital,Qods square

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3333 4807

Email

fereshteh.sobhani23@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Fershteh Sobhani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Qods hospital,Qods square

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3333 4807

Email

fereshteh.sobhani23@gmaile.com

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

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

Title and more details about the data/document

The analysis result of all data can be detected and tracked.

When the data will become available and for how long

6 months after printing the results.

To whom data/document is available

All researchers.

Under which criteria data/document could be used

To conduct further research in the future.

From where data/document is obtainable

To Research Center of Qazvin University of Medical Sciences.

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

Administrative and academic process according to university rules.

Comments