Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Sep 2026

Comparison of the efficacy of two therapeutic regimens for primary nocturnal enuresis; oxybutnin plus desmopressin versus desmopressin in pediatric patients

Protocol summary

Summary

Our aim in this study is to compare the efficacy of two therapeutic regimens for primary nocturnal enuresis; oxybutnin plus desmopressin versus desmopressin in pediatric patients. In a unicentral randomized trial 60 patients with age of 5 to 18 years from both genders with primary nocturnal enuresis referring to the nephrology clinic of Tabriz Children's hospital will be assigned in two equal-sized groups to receive combination of nasal desmopressin and oxybutinin or nasal desmopressin alone. Desmopressin spray will be administered 1 puff/night for all the patients and oxybutinin 0.5 to 1 tablet 3 times a day as needed. Inclusion criteria are to have primary nocturnal enuresis and being 5 to 18 years old. Exclusion criteria are to have neurogenic bladder; CNS disorders; secondary nocturnal enuresis. Three months after drug consumption patients in the groups would be evaluated in terms of presence of nocturnal enuresis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301117892N4**
Registration date: **2013-01-28, 1391/11/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-28, 1391/11/09

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-08-31, 1391/06/10

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of two therapeutic regimens for primary nocturnal enuresis; oxybutnin plus desmopressin versus desmopressin in pediatric patients

Public title

Comparison of the efficacy of two therapeutic regimens for primary nocturnal enuresis; oxybutnin plus desmopressin versus desmopressin in pediatric patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (5 to 18 year-old patients with primary nocturnal enuresis) Exclusion criteria: (to have neurogenic bladder; CNS disorders; secondary nocturnal

enuresis; occurrence of drug side effects)

Age
From **5 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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 Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square

City
Tabriz

Postal code

Approval date
2012-08-29, 1391/06/08

Ethics committee reference number
9158

Health conditions studied

1

Description of health condition studied
Primary nocturnal enuresis

ICD-10 code
F98.0

ICD-10 code description
Nonorganic enuresis

Primary outcomes

1

Description
Frequency of nocturnal urination in a week

Timepoint
weekly for 12 weeks

Method of measurement
Using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In combination therapy group: Desmopressin nasal spray will be administered 1 puff/night and oxybutinin 0.5 to 1 tablet 3 times a day as needed for three months.

Category
Treatment - Drugs

2

Description
In one-drug group: Desmopressin nasal spray will be administered 1puff/night for 3 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children's Hospital

Full name of responsible person
Anoosh Azarfar, Assistant professor, Subspecialist in children's nephrology

Street address
Children's Hospital, Sheshgelan st.

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Alireza Ostad Rahimi

Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square

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Tabriz

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
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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