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

Country

Iran (Islamic Republic of)

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+98 51 1606 1227

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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

City

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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Anoosh Azarfar

Position

Assistant professor, subspecialist in children's nephrology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Scinces

Full name of responsible person

Mehdi Hemmati

Position

General physician

Other areas of specialty/work

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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