

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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 Azarfara

###### Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1606 1227

##### Email address

azarfara@mums.ac.ir

##### 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, Sheshgela 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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Children's Hospital, Sheshgelan st.

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azarfar132@yahoo.com

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**Position**

Assistant professor, subspecialist in children's

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**Other areas of specialty/work**

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Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Hemmati

**Position**

General physician

**Other areas of specialty/work**

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mehdi.hemmati@rocketmail.com

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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*