

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Clinical trial of Effects of using low-dosage Imipramine and Desmopressin with normal dosage on nocturnal enuresis in children with a resistance against Desmopressin

#### Protocol summary

##### Summary

Study goal: Studying the treatment effects of Desmopressin and low-dosage Imipramine with Desmopressin in treatment of primary nocturnal enuresis in children. Study population of 40 patients of Dr. Sheikh Hospital in Mashhad will randomly be divided into two groups (after getting their approvals). Inclusion criteria are primary nocturnal enuresis and being over 6 years old. In case of drug side effects and not completing the treatment period the patient will be excluded from the study. Patients who are not treated after one month from using Desmopressin will be included in the study. First group will be receiving a compound of Desmopressin and low-dosage Imipramine (5 mg), while the second group will be treated with Desmopressin only. In case no response is achieved after 3 weeks of receiving Desmopressin, the treatment shall be stopped. According to the guideline, the drug can be used up to 3 months. The main goal of present study is to study the effects of drugs on nocturnal enuresis in children.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016082129459N1**

Registration date: **2017-09-03, 1396/06/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-03, 1396/06/12

##### Registrant information

###### Name

Elham Zahabi

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3767 0507

##### Email address

zahabie891@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Vice-President of Mashhad Medical Sciences University

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of Effects of using low-dosage Imipramine and Desmopressin with normal dosage on nocturnal enuresis in children with a resistance against Desmopressin

##### Public title

Effects of using low-dosage Imipramine and normal-dosage Desmopressin on nocturnal enuresis in children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: primary nocturnal enuresis with single symptom; being of above 6 age; not having a kidney

disorder; not having neurogenic bladder dysfunction; not being treated after using Desmopressin for one month. Exclusion criteria: drug side effects; not completing the treatment period; allergy to Imipramine; suffering from heart disorder; suffering from heart arrhythmia.

#### Age

From **6 years** old to **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Randomization Method: Random Number Table

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

##### City

Mashhad

##### Postal code

#### Approval date

2016-01-16, 1394/10/26

#### Ethics committee reference number

IR.MUMS.fm.REC.1394.610

## Health conditions studied

### 1

#### Description of health condition studied

enuresis

#### ICD-10 code

R32

#### ICD-10 code description

Unspecified urinary incontinence

## Primary outcomes

### 1

#### Description

Bed wetting

#### Timepoint

Number of not bed wetting of the patient will be evaluated at baseline, 2 weeks later, 1 month later and then monthly until 6 months

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Prescribed Desmopressin and 5 mg of Imipramine

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Prescribed Desmopressin

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad Dr.Sheikh Hospital

##### Full name of responsible person

Anoosh Azarfar, Associated professor, Subspecialist in children's nephrology

##### Street address

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

##### City

Mashhad

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Anoosh Azarfar

**Position**

Associated professor, subspecialist in children's nephrology

**Other areas of specialty/work**

**Street address**

Dr. Sheikh Hospital, Tohid Square, Motahari Avenue

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3726 9021

**Fax**

**Email**

azarfara@mums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Anoosh Azarfar

**Position**

Subspecialist in children's nephrology

**Other areas of specialty/work**

**Street address**

Dr. Sheikh Hospital, Tohid Square, Motahari Avenue

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3726 9021

**Fax**

**Email**

azarfara@mums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Elham Zahabi

**Position**

Medical student

**Other areas of specialty/work**

**Street address**

Dr. Sheikh Hospital, Tohid Square, Motahari Avenue

**City**

Mashhad

**Postal code**

**Phone**

**Fax**

**Email**

zahabie891@mums.ac.ir

**Web page address**

**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*