

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Azarfara

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 Azarfara

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