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 Azarfar

Position

Associated professor, subspecialist in children's nephrology

Other areas of specialty/work

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Dr. Sheikh Hospital, Tohid Square, Motahari Avenue

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Dr. Anoosh Azarfar

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Subspecialist in children's nephrology

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Person responsible for updating data

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Name of organization / entity

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Elham Zahabi

Position

Medical student

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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