# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 2026

## Comparison of the effectiveness of medicinal(desmopressin) and non-medicinal(alarm) therapy on the control of nocturnal enuresis of children

## Protocol summary

**Study aim**

effectiveness of medicinal and non-medicinal therapy on the control of primary nocturnal enuresis of children in nephrology clinic of Mashhad Dr.Sheikh Hospital

**Design**

A desmopressin spray dispensing group will use the desomex that made in iran, and the dosage will be used every night (one papaya per nose) and the second group will be treated with non-medicated alarms or night bells and treated for a period of The month will continue and the number of nights will be calculated within one month

**Settings and conduct**

enuresis is a type of incontinence in children that appears in the form of a little and sudden wetness and is determined by unintentional depletion of bladder with normal function of bladder at other hours. This study is going to be carried out in Dr.Sheikh Hospital of Mashhad. There will be thorough neural and physical examination and assessment for all children. No blinding is done in the study. Finally after a month of drug use, patients will be evaluated from a medical response point of view. Medical response is then divided to 3 levels as following: 1-no response 2- relative response as reduction of incontinence numbers to half and 3- complete improvement

**Participants/Inclusion and exclusion criteria**

All children with enuresis and 6 to 18 years old will be included in the study and children with neurologic urinary disorders, congenital anomalies and obstruction issues will be excluded

**Intervention groups**

A desmopressin spray will be used every night (one puff per nose) and the second group will be treated with non-medicated alarms or night bells

**Main outcome variables**

Rate of control and improvement of incontinence after use of alarm vs desmopressin

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180428039453N1**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-09, 1397/04/18**
Update count: **0**

**Registration date**

2018-07-09, 1397/04/18

**Registrant information**

**Name**

Oveis Iraninejad

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3865 4416

**Email address**

iranio901@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-09-23, 1396/07/01

**Expected recruitment end date**

2019-02-20, 1397/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of medicinal(desmopressin) and non-medicinal(alarm) therapy on the control of nocturnal enuresis of children

**Public title**
Comparison of the effectiveness of medicinal and non-medicinal therapy on the control of nocturnal enuresis of children
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
children with primary enuresis with 6 to 18 years old completion of informed consent form no existence of urological diseases
**Exclusion criteria:**
patients with neurogenic bladder congenital disorders of urinary system urinary tract obstruction neurological disorders such as myelomenoncule unwillingness to participate in the study
**Age**
From **6 years** old to **18 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Using table of random numbers and envelope method, patients will be divided to two groups
**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 Mashhad University of Medical Sciences
**Street address**
Taheri Ave, Tohid Square, Dr. Sheikh Hospital,
**City**
mashhad
**Province**
Razavi Khorasan
**Postal code**
1358- 91735
**Approval date**
2017-03-10, 1395/12/20
**Ethics committee reference number**
IR.MUMS.fm.REC.1395.634

## Health conditions studied

### 1

**Description of health condition studied**
urinary incontinence
**ICD-10 code**
R39.81
**ICD-10 code description**
Functional urinary incontinence

## Primary outcomes

### 1

**Description**
Rate of control and improvement of incontinence after use of enuresis alarm vs desmopressin
**Timepoint**
A month after use of enuresis alarm
**Method of measurement**
The therapeutic response will be divided into three levels more effectively and without any difference and less effect

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Control group: This group contain of 10 patients will use desmopressin spray with the traditional name of desmex that made in iran, and the dosage will be used every night (one puff per nose)for a month.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group:this group contain of 10 patients will be treated with non-medicated alarms or night bells and treated for a period of The month will continue and the number of nights will be calculated within one month
**Category**
Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Mashhad Dr.Sheikh Hospital

**Full name of responsible person**
Anoosh Azarfar

**Street address**
Taheri Ave, Tohid Square, Dr. Sheikh Hospital

**City**
mashhad

**Province**
Razavi Khorasan

**Postal code**
1358- 91735

**Phone**
+98 51 3726 9021

**Email**
azarfara@mums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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

**Province**
Razavi Khorasan

**Postal code**
91778-99191

**Phone**
+98 51 3841 1538

**Email**
ramresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Mashhad University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Anoosh Azarfar

**Position**
Associated professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Pediatrics

**Street address**
Taheri Ave, Tohid Square, Dr. Sheikh Hospital

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
All data can be shared after patients are made unidentifiable
**When the data will become available and for how long**
Data can be accessible 6 months after results are published
**To whom data/document is available**
Data will be available for researchers in universities and other scientific institutes
**Under which criteria data/document could be used**
Carrying out analysis on data is permitted
**From where data/document is obtainable**
Data can be accessible through sending an email to the corresponding author
**What processes are involved for a request to access data/document**
After sending a request email to the corresponding author, data will be sent in 1 month
**Comments**