

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 myelomenonucle 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

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Razavi Khorasan

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1358- 91735

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+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

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91778-99191

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+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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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