

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effectiveness of Desmopressin-Oxybutynin with Fluvoxamine in Treatment of Nocturnal Enuresis in Children referring to Nephrology Clinic

Protocol summary

Study aim

Comparison of the Effectiveness of Desmopressin-Oxybutynin with Fluvoxamine in Treatment of Nocturnal Enuresis in Children referring to Nephrology Clinic

Design

In this study, all patients Older than eight years old with Nocturnal Enuresis resistant to behavioral therapy & first-line medication therapy who refer to Nephrology Clinic, after being informed and acquisition of consent, will be included in the study.

Settings and conduct

Primary Nocturnal Enuresis is the involuntary discharge of urine at night by children old enough to be expected to have bladder control and bladder control has never been attained. 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 divided to 3 levels as following: 1-no response 2- relative response as reduction of nocturnal enuresis to less than 2 times in a month and 3- complete improvement

Participants/Inclusion and exclusion criteria

All patients Older than eight years old with Nocturnal Enuresis resistant to behavioral therapy & first-line medication therapy will be included in the study and children with Major Depression Disorder, Anxiety, etc will be excluded.

Intervention groups

Intervention group: En Intervention group: Patients are prescribed 25 milligram of Fluvoxamine nightly for one month. Control group: Patients will be given Oxybutynin drug with dose of 0.1 milligram per kilogram and Desmopressin 10 to 20 microgram intranasal for one month

Main outcome variables

Rate of control and improvement of nocturnal enuresis after use of Fluvoxamine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171112037417N1**

Registration date: **2018-05-20, 1397/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-20, 1397/02/30**

Update count: **0**

Registration date

2018-05-20, 1397/02/30

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 517602947

Email address

alizadeha901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-25, 1397/02/05

Expected recruitment end date

2018-06-26, 1397/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Desmopressin-Oxybutynin with Fluvoxamine in Treatment of Nocturnal Enuresis in Children referring to Nephrology Clinic

Public title

Comparison of the Effectiveness of Desmopressin-Oxybutynin with Fluvoxamine in Treatment of Nocturnal Enuresis in Children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Older than eight years old patients with Nocturnal Enuresis resistant to behavioral therapy & first-line medication therapy

Exclusion criteria:

Patients with Major Depression Disorder, Anxiety, etc

Age

From **8 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

2017-10-11, 1396/07/19

Ethics committee reference number

IR.MUMS.sm.REC.1396412

Health conditions studied**1****Description of health condition studied**

Nocturnal Enuresis

ICD-10 code

F98.0

ICD-10 code description

Enuresis not due to a substance or known physiological condition

Primary outcomes**1****Description**

Rate of control and improvement of nocturnal enuresis after use of Fluvoxamine

Timepoint

A month after use of Fluvoxamine

Method of measurement

Medical response is divided to 3 levels as following: 1-no response 2- relative response as reduction of nocturnal enuresis to less than 2 times in a month and 3- complete improvement

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients are prescribed 25 milligram of Fluvoxamine nightly for one month

Category

Treatment - Drugs

2**Description**

Control group: Patients will be given Oxybutynin drug with dose of 0.1 milligram per kilogram and Desmopressin 10 to 20 microgram intranasal for one month

Category

Treatment - Drugs

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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