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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Taheri Ave, Tohid Square, Dr. Sheikh Hospital

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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