

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of comparison of the efficacy of Tolterodine versus Oxybutynin in treatment of enuretic children resistant to Desmopressin

Protocol summary

Study aim

Determine and compare the effects of tolterodine treatment with oxybutynin in the treatment of enuretic children resistant to Desmopressin

Design

Triple blind randomized clinical trial without control group, community-based, with parallel groups, alternately randomization of the patients and a sample size of 61 ones.

Settings and conduct

Primary nocturnal enuresis patients who did not respond to desmopressin therapy and referred to the Booali hospital pediatric nephrology clinic are randomly divided into two groups of tolterodine + desmopressin or oxybutynin + desmopressin for three months. The patients' response to treatment will be checked 6 weeks after the start of treatment and at the end of the 12th week in the form of telephone follow-up or in-person interviews and complications of the drug will be recorded. The patient, investigator and the data analyser will not be aware of the drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primary enuresis; no evidence of secondary enuresis in clinical examinations and urinalysis and sonography; no response to Nasal Desmopressin. Exclusion criteria: secondary enuresis; underlying genitourinary system anomalies; interruption of follow up of the patient

Intervention groups

Group 1 children that will receive Oxybutynin besides desmopressin and Group 2 children that will receive tolterodine besides desmopressin.

Main outcome variables

The frequency of enuresis in night; frequency of enuresis in a week; response to treatment in a week; response to treatment in a night; drug side effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141224020419N3**

Registration date: **2019-07-02, 1398/04/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-02, 1398/04/11**

Update count: **0**

Registration date

2019-07-02, 1398/04/11

Registrant information

Name

Hamid Mohammadjafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3331 3866

Email address

hmjafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of the efficacy of Tolterodine versus Oxybutynin in treatment of enuretic children resistant to Desmopressin

Public title

Efficacy of Tolterodine versus Oxybutynin in treatment of enuresis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primary enuresis No evidence of secondary enuresis in clinical examination, urine analysis and sonography No response to nasal desmopressine

Exclusion criteria:

Secondary enuresis Underlying genitourinary system anomalies Interruption of follow up of the patient

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be divided into two groups with statistical software receiving Tolterodine plus desmopressin or oxybutynin plus desmopressin for three months by simple randomization method

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient, investigator, and data analyzer will not be aware about the type of drug

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Māzandarān University of Medical Sciences

Street address

Moalem

City

Sari

Province

Mazandaran

Postal code

4818856361

Approval date

2019-05-18, 1398/02/28

Ethics committee reference number

IR.mazums.rec.1398.219

Health conditions studied

1

Description of health condition studied

Nocturnal enuresis

ICD-10 code

R32

ICD-10 code description

Unspecified urinary incontinence

Primary outcomes

1

Description

Nocturnal enuresis in night

Timepoint

Beginning of the study, 6 and 12 weeks after beginning of the study

Method of measurement

The frequency of wetting every night

2

Description

Nocturnal enuresis in week

Timepoint

Beginning of the study, 6 and 12 weeks after beginning of the study

Method of measurement

The frequency of wetting in week

Secondary outcomes

empty

Intervention groups

1

Description

Intervention first group: The group receiving tolterodine (Made by Iran Daroo Co, 05-4 mg every night) 0.5 mg every night after dinner than could be titrated to 4 mg + desmopressin (Made by Iran Daroo Co, with dose of one 10 microgram puff on one side of the nose every night before bed which increase to two puffs of 20 microgram on every nose based on clinical response) for 12 weeks

Category

Treatment - Drugs

2

Description

The second intervention group: The group receiving oxybutynin (Made by Iran Daroo Co, 0.2 mg/kg every night before bed)+ desmopressin (Made by Iran Daroo Co, with dose of one 10 microgram puff on one side of the nose every night before bed which increase to two puffs of 20 microgram on every nose based on clinical response) for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nephrology clinic of Bouali Hospital of Sari

Full name of responsible person

Hamid Mohammad Jaafari, MD

Street address

Booali hospital, Pasdaran boulevard, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4815838477

Phone

+98 11 3334 2334

Fax

+98 11 3334 2334

Email

hamidmjaafari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Vice chancellor for research of Mazandaran university of medical sciences, Moalem square, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4818856361

Phone

+98 11 3334 2334

Fax

+98 11 3448 4800

Email

saeedi_m_2001@yahoo.com

Grant name

Majid Saeedi

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Hamid Mohammadjaafari

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Booali hospital, Pasdaran boulevard, Sari

City

Sari

Province

Mazandaran

Postal code

4815838477

Phone

+98 11 3334 2334

Email

hamidmjaafari@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Neda Ezoddin

Position

Resident of Pediatrics

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Booali hospital, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 2334
Email
nezoddin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Neda Ezoddin
Position
Resident of Pediatrics
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Booali hospital, Pasdaran Boulevard, Sari
City

Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 2334
Email
nezoddin@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable