

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of combination therapy with desmopressin plus tolterodine and desmopressin plus indomethacin for the treatment of pediatric enuresis

Protocol summary

Study aim

Comparison of desmopressin plus tolterodine with desmopressin plus indomethacin for the treatment of pediatric enuresis

Design

Two arm phase 2 parallel group randomized open-label trial of 40 patients, with randomization done using the Random Allocation software.

Settings and conduct

This open-label randomized clinical trial included children aged >5 and <18 years with mono- or disymptomatic enuresis referred to the Nephrology Clinic of Bandar Abbas Children's Hospital. Children in the desmopressin plus tolterodine group received 60 mcg desmopressin plus 2 mg tolterodine every night before bedtime and children in the desmopressin plus indomethacin group received 60 mcg desmopressin plus 50 mg indomethacin every night before bedtime. Response to treatment was compared between groups 1, 3, and 5 months after the initiation of treatment.

Participants/Inclusion and exclusion criteria

Inclusion: Age >5 and <18 years, diagnosis of mono- (nocturnal) or disymptomatic (nocturnal and diurnal) enuresis Exclusion: Having previously received any treatment for enuresis, secondary causes of enuresis

Intervention groups

Desmopressin plus tolterodine group: 60 mcg desmopressin and 2 mg tolterodine every night before bedtime Desmopressin plus indomethacin group: 60 mcg desmopressin and 50 mg indomethacin every night before bedtime

Main outcome variables

Response to treatment in the form of the number of dry nights per month

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210613051564N1**

Registration date: **2021-07-19, 1400/04/28**

Registration timing: **retrospective**

Last update: **2021-07-19, 1400/04/28**

Update count: **0**

Registration date

2021-07-19, 1400/04/28

Registrant information

Name

Maryam Esteghamati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 7690

Email address

maryamesteghamati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2019-03-21, 1398/01/01

Trial completion date

2019-03-21, 1398/01/01

Scientific title

Comparison of combination therapy with desmopressin plus tolterodine and desmopressin plus indomethacin for the treatment of pediatric enuresis

Public title

Desmopressin plus tolterodine versus desmopressin plus indomethacin for pediatric enuresis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age >5 years and <18 years Diagnosis of mono- or disymptomatic enuresis

Exclusion criteria:

Having previously received any treatment for enuresis
Secondary causes of enuresis, including anatomic disorders of the urinary system, trauma, constipation, diabetes mellitus, diabetes insipidus, urinary tract infection, and the like.

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done by simple randomization using the randomization table generated by the Random Allocation software with individuals as the unit of randomization. This table contained numbers from 1 to 40 and in front of each number the name of either of the groups were randomly mentioned. Based on this table, the study groups were written in sealed envelopes numbered from 1 to 40 and each envelope was allocated to a single patient in order of their entrance to the study.

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 Hormozgan University of Medical Sciences

Street address

Technology and Research Vice-chancellery, East side of Payambar Azam Hospital, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2018-05-13, 1397/02/23

Ethics committee reference number

IR.HUMS.REC.1397.070

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

Pediatric enuresis

ICD-10 code

N39.44

ICD-10 code description

Nocturnal enuresis

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

Response to treatment in the form of the number of dry nights per month

Timepoint

1, 3, and 5 months after the initiation of treatment

Method of measurement

By asking the children's parents

Secondary outcomes

empty

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

Intervention group: Desmopressin plus tolterodine: A 60 mcg desmopressin tablet from Ferring Pharmaceuticals Ltd., United Kingdom, and a 2 mg tolterodine tablet from Alhavi Pharmaceutical Co., Iran, every night before bedtime

Category

Treatment - Drugs

2**Description**

Intervention group: Desmopressin plus indomethacin: A 60 mcg desmopressin tablet from Ferring Pharmaceuticals Ltd., United Kingdom, and two 25 mg

indomethacin capsules from Loghamn Pharmaceutical & Hygienic Co., Iran, every night before bedtime

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Abbas Children's Hospital

Full name of responsible person

Maryam Esteghamati

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Bandar Abbas Children's Hospital, Imam Khomeini Blvd., Bandar Abbas

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Technology and Research Vice-chancellery, Hormozgan 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

Sponsors / Funding sources

1

Sponsor

Grant name

Grant code / Reference number

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

empty

Title of funding source

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Technology and Research Vice-chancellery, Hormozgan University of Medical Sciences

Full name of responsible person

Nasrin Davari Dolatabadi

Street address

Technology and Research Vice-chancellery, East side of Payambar Azam Hospital, Bandar Abbas

City

Person responsible for general inquiries

Contact

Name of organization / entity

Bandar Abbas Children's Hospital

Full name of responsible person

Seyedeh Elaheh Mousavipour

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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 collected data will be available after deidentification.

When the data will become available and for how long

Data will be available in 2022.

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Eligible individuals will be able to use the data for pooled analysis

From where data/document is obtainable

Via an email address: maryamesteghamati@gmail.com to Dr. Maryam Esteghamati

What processes are involved for a request to access data/document

Within a month of presenting a valid identification card

Comments