

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the Effectiveness of Hydrochlorothiazide with Nasal Spray of Desmopressin in Treatment of Nocturia in Children Referring to Pediatric Nephrology Clinic in hamadan in first 6 month of 2019

Protocol summary

Study aim

Determining the efficacy of hydrochlorothiazide in the treatment of nocturnal enuresis children in Hamadan province

Design

All patients with a diagnosis of primary nocturnal enuresis according to the age and sex enrolled to study Based on the inclusion criteria for entry and absence of exclusion criteria, and after obtaining informed consent, they are included in the study and according to the protocol on treatment of nocturnal enuresis in two groups, the control group and the case group are based on gradual and sequential outcome by simple randomization and double blind The control group is based on the current protocol of nasal spray desmopressin 10-20 micrograms at the bed time .In the case group patients undergoing thiazide diuretics hydrochlorothiazide 1mg/kg at the morning in single dose placed.

Settings and conduct

A clinical trial study performed in Hamedan in girls over 5 years of age and boys over 6 years of age with primary nocturnal enuresis

Participants/Inclusion and exclusion criteria

Having inclusion criteria and no exclusion criteria

Intervention groups

Use of hydrochlorothiazide in the case group for the treatment of enuresis in children The control group is based on the current protocol of nasal spray desmopressin 10-20 micrograms at the bed time .In the case group patients undergoing thiazide diuretics hydrochlorothiazide 1mg/kg at the morning in single dose placed.

Main outcome variables

Resolved of Enuresis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181212041936N1**

Registration date: **2019-01-23, 1397/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

Registration date

2019-01-23, 1397/11/03

Registrant information

Name

rahimpour amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3264 0042

Email address

r.amiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Hydrochlorothiazide with Nasal Spray of Desmopressin in Treatment of Nocturia in Children Referring to Pediatric Nephrology Clinic in hamadan in first 6 month of 2019

Public title

Comparison of the Effectiveness of Hydrochlorothiazide with Nasal Spray of Desmopressin in Treatment of Nocturia in Children Referring to Pediatric Nephrology Clinic in hamadan in first 6 month of 2019

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All girls aged more than 5 years old and all boys over 6 years of age with diagnosis of primary monosymptomatic nocturnal enuresis referred to the nephrology clinic of children

Exclusion criteria:

Anatomical disorders lead to urinary incontinence such as neurogenic bladder, posterior ureteral valve and anatomical disorders of the ureter Metabolic disorders leading to polyuria such as diabetes mellitus and diabetes insipid secondary nocturnal enuresis polysymptomatic nocturnal enuresis Parental dissatisfaction adverse effects of drugs

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **208**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, block

Blinding (investigator's opinion)

Double blinded

Blinding description

The two groups of the control group and the case group are included in the study according to the simple sequential randomization method. The investigator and the patients do not know how to enter the groups, and the individuals enter the group with the code. The control and case groups are also coded and only Analysts are aware

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamedan university of medical sciences., No. 65178, Shahid fahmide Ave., Hamadan Province., Hamadan Town, Iran

City

Hamadan

Province

Hamadan

Postal code

6514845471

Approval date

2018-11-30, 1397/09/09

Ethics committee reference number

IR.UMSHA.REC.1397.627

Health conditions studied

1

Description of health condition studied

Enuresis

ICD-10 code

F98.0

ICD-10 code description

Nonorganic enuresis

Primary outcomes

1

Description

Resolved of Enuresis

Timepoint

Patients are followed up for a period of 6 months, and the outcome of the disease is the drying up of the child during sleep during medication three months and within three months after it, after discontinuation of drugs, in addition to monthly monitoring during the monthly visits to the families It will be explained if the child reports wetting the next day and if the child remains dry. Meanwhile, after the discontinuation of the medications within the next three months, follow-up and drying or returning of the enuresis will be considered.

Method of measurement

Completion of follow-up questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: hydrochlorothiazide

Category

Treatment - Drugs

2

Description

Control group: nasal spray desmopressin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Nephrology Clinic

Full name of responsible person

Fahimeh Ahmadvand

Street address

Besat hospital., ShahidBeheshti Blv., District2.,
Motahary Blv., Hamedan Town,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fahimeh Ahmadvand

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Rahimpour Amiri

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

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

Hamedan University of Medical Sciences

Full name of responsible person

Fahimeh Ahmadvand

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner