Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 athe 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 inclusioncriteria and no exclusion hcriteria

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 athe 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 Enoresis

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., Hamedan 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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Fax
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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
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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