

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Study the clinical effect of berry extract and comparison with Desmopressin in 6-12 children with primary mono symptomatic nocturnal enuresis

Protocol summary

Study aim

1. Study the effect of berry extract in mono symptomatic Nocturnal Enuresis treatment
2. Comparison the effect of berry extract with desmopressin spray in mono symptomatic Nocturnal Enuresis treatment

Design

A non-randomized, non-blinded clinical study without placebo control in phase 2 clinical trial will be conducted. Seventy children (6-12 years old) with mono-symptomatic Nocturnal Enuresis will be studied in two parallel groups and will be followed for 4 weeks in one clinical center.

Settings and conduct

A non-blinded and non-randomized clinical study will be done on seventy children in two parallel groups with mono symptomatic Nocturnal Enuresis in a clinical center. The berry extract syrup will be administered for one group, While another group will be under treatment by Desmopressin spray. Two groups will be monitored and assessed for 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children between 6-12 years old; Satisfied parents for participating in study; Not suffered from incurable and underlying disease; Suffered from mono symptomatic Nocturnal Enuresis
Exclusion criteria: Children out of range 6-12 years old; Lack of permission of parents for participating in study; Suffered from incurable and underlying disease; Not suffered from mono symptomatic Nocturnal Enuresis

Intervention groups

Control group: Desmopressin administration based on medical practitioner order as a treatment of mono symptomatic Nocturnal Enuresis
Intervention group: berry extract syrup (7.5 ml twice a day), is equal to 20 grams of fruit per day

Main outcome variables

Frequency of wet nights in a week
Age of the children

Sexuality of the children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N11**

Registration date: **2022-09-15, 1401/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-15, 1401/06/24**

Update count: **0**

Registration date

2022-09-15, 1401/06/24

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2022-07-22, 1401/04/31

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the clinical effect of berry extract and comparison with Desmopressin in 6-12 children with primary mono symptomatic nocturnal enuresis

Public title

Comparison the clinical effect of berry extract and Desmopressin in primary mono symptomatic nocturnal enuresis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children between 6-12 years old Satisfied parents for participating in study. Not suffered from incurable and underlying disease Suffered from mono symptomatic nocturnal enuresis

Exclusion criteria:

Children out of range 6-12 years old Lack of permission of parents for participating in study Suffered from incurable and underlying disease Not suffered from mono symptomatic nocturnal enuresis

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Investigation Center of Chronic Kidney Diseases in children

Street address

Children medical clinic, Next to the Imam Khomeini Hospital, Dr Gharib Avenue, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2022-04-14, 1401/01/25

Ethics committee reference number

IR.TUMS.CHMC.REC.1401.031

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

Mono-symptomatic nocturnal enuresis

ICD-10 code

N39.44

ICD-10 code description

Overflow Reflex Urge incontinence

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

Frequency of wet nights in a weekchildren

Timepoint

Before intervention and 4 weeks after beginning the intervention and 2 weeks after cessation of intervention

Method of measurement

Parent's report in questionnaire

Secondary outcomes

empty

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

Intervention group: Berry hydroalcoholic extract syrup (7.5 ml twice a day), is equal to 20 grams of fruit per day, for 2 consecutive weeks

Category

Treatment - Drugs

2**Description**

Cōntrōl group: Desmopressin (nasal spray 10 microgram per dose) administration based on medical practitioner order for 4 consecutive weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children medical clinic

Full name of responsible person

Dr. Arash Abbasi

Street address

Children medical clinic, Next to the Imam Khomeini Hospital, Dr Gharib Avenue, Keshavarz Blvd

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a-abbasi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahdi Vazirian

Street address

Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.

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vazirian_m@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

PhD of pharmacognosy

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Vazirian_m@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Demographic specification of patients, would be published, except their names and address. Primary outcome of the patients would be published, too.

When the data will become available and for how long

Data would be available 6 months after publishing the results

To whom data/document is available

Data would be available for researchers in academic and scientific organisations

Under which criteria data/document could be used

Any type of usage of data is allowable, except using for manufacturing a product

From where data/document is obtainable

Sending an E. mail to mehdivazirian@gmail.com

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

After receiving E. mail, data would be sent within a week

Comments