

# 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

**City**

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**Province**

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**Postal code**

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**Phone**

+98 21 6147 3174

**Email**

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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614315

**Phone**

+98 21 8889 6696

**Email**

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

**Street address**

Faculty of pharmacy, 16th Azar Ave., Enqelab Ave.

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**Province**

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**Postal code**

1417614411

**Phone**

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**Fax****Email**

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**

Mahdi Vazirian

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## Person responsible for updating data

#### Contact

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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**