

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation effect of vitamin B complex in the treatment of primary nocturnal enuresis

#### Protocol summary

##### Study aim

Aim will evaluation effect of vitamin B complex in the treatment of primary nocturnal enuresis.

##### Design

This evaluation is a phase 3 clinical trial. Children with diagnosis of primary nocturnal enuresis and approved by a specialist will considered as a study group. In this study, 70 children who met the inclusion criteria will selected. Patients will non-randomly assigned to two groups, 35 children in the B complex vitamin group and 35 children in the control group. Accordingly, treatment lasted 60 days and the frequency of enuresis before and after treatment will recorded.

##### Settings and conduct

This study will carried out as a clinical trial at the Pediatric Clinic of Amir Kabir Hospital in Arak, Also the study will also be not blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included as children with primary nocturnal enuresis with age higher than 5 years of age, who were willing to participate in the study. Also exclusion criteria included previous nocturnal enuresis and receiving related treatments.

##### Intervention groups

In the intervention group, in addition to desmopressin spray with a dose of 10 micrograms every night before sleep, B complex vitamin will used at a dose of 1 tablet per day for 60 days. Also in control group, desmopressin with a dose of 10 micrograms every night before sleep used along with educating parents and children.

##### Main outcome variables

Frequency of nocturnal enuresis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201028049172N1**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

##### Registration date

2021-11-16, 1400/08/25

##### Registrant information

###### Name

Sahar Alimoradi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 4222 6774

###### Email address

sahar.alimoradi70.sa@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-22, 1400/07/30

##### Expected recruitment end date

2022-06-21, 1401/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation effect of vitamin B complex in the treatment of primary nocturnal enuresis

##### Public title

Evaluation of the effect of vitamin B complex on nocturnal enuresis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Children with primary enuresis Age more than 5 years of age Satisfaction to participate in the study

### Exclusion criteria:

History of enuresis Receive enuresis-related treatments

## Age

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

## Gender

Both

## Phase

3

## 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 Arak University of Medical Sciences

##### Street address

Sardasht

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2021-09-21, 1400/06/30

#### Ethics committee reference number

IR.ARAKMU.REC.1400.142

## Health conditions studied

### 1

#### Description of health condition studied

Primary nocturnal enuresis

## ICD-10 code

N39.44

## ICD-10 code description

Nocturnal enuresis

## Primary outcomes

### 1

#### Description

Frequency of nocturnal enuresis

#### Timepoint

Before treatment and 2 months after starting treatment

#### Method of measurement

Based on checklist

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, in addition to desmopressin spray with a dose of 10 micrograms every night before sleep, B complex tablet is used as a dose of 1 tab per day for 60 days.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In this group, only desmopressin with a dose of 10 micrograms every night before sleep is used.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Kabir Hospital

##### Full name of responsible person

Sahar Alimoradi

##### Street address

3819693345, Amir Kabir Hospital, Basij Square, Arak.

##### City

Arak

##### Province

Markazi

##### Postal code

3819693345

##### Phone

+98 86 3321 4418

##### Email

saharalimoradi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Arash Anoushirvani

**Street address**

3819693345, Vice Chancellor for Research, Arak University of Medical Sciences, Sardasht, Arak.

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+98 86 3313 5075

**Email**

Anoushirvani@yahoo.com

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

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Parsa Yousefichaijan

**Position**

University professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric Nephrology

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Pasture Institute of Iran

**Full name of responsible person**

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**Position**

University professor

**Latest degree**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate Professor of Pediatric Nephrology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric Nephrology

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**Postal code**

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**Email**

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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