

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

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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

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3819693345, Amir Kabir Hospital, Basij Square, Arak.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

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 updating data

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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