

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the Effect of Folic Acid on the Treatment of Primary Nocturnal Enuresis.

#### Protocol summary

##### Study aim

The aim was to evaluate the effect of folic acid in the treatment of primary enuresis.

##### Design

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

##### Settings and conduct

This study will be 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, folic acid is used at a dose of 1 mg 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: **IRCT20130518013366N14**

Registration date: **2020-11-06, 1399/08/16**

Registration timing: **retrospective**

Last update: **2020-11-06, 1399/08/16**

Update count: **0**

##### Registration date

2020-11-06, 1399/08/16

##### Registrant information

###### Name

Parsa Yousefi Chaijan

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1312 1964

###### Email address

dr.yousefi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-10, 1398/06/19

##### Expected recruitment end date

2020-05-08, 1399/02/19

##### Actual recruitment start date

2019-09-10, 1398/06/19

##### Actual recruitment end date

2020-05-08, 1399/02/19

##### Trial completion date

2020-05-08, 1399/02/19

##### Scientific title

Evaluation of the Effect of Folic Acid on the Treatment of Primary Nocturnal Enuresis.

##### Public title

Evaluation Effect of Folic Acid 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**

Actual sample size reached: **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

2019-01-28, 1397/11/08

#### Ethics committee reference number

IR.ARAKMU.REC.1397.314

## 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, folic acid is used as a dose of 1 mg 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, along with parent and child education.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

##### Full name of responsible person

Masoud Rezagholizamenjany

##### Street address

3819693345, Amir Kabir Hospital, Basij Square, Arak.

##### City

Arak

##### Province

Markazi

##### Postal code

3819693345

##### Phone

+98 86 3457 3785

##### Email

## 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.

**City**

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**Province**

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3819693345

**Phone**

+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**

Associate Professor of Pediatric Nephrology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric Nephrology

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## Person responsible for scientific inquiries

#### Contact

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Arak University of Medical Sciences

**Full name of responsible person**

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**Position**

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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