

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)

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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.

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3819693345

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Ali Arash Anoushirvani

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

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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 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