

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Nutritional Factors in the Treatment of Primary Nocturnal Enuresis in Children

Protocol summary

Summary

Objectives: Primary nocturnal enuresis is one of the most common and important problems in school-aged children. This disorder can induce problems range from behavioral problems, psychosocial for the child. Design: This study is a clinical trial that performed on children 5-12 years old and suffering from nocturnal enuresis (Involuntary excretion of urine at night more than 2 times per week for 3 months in children over 5 years is considered to be nocturnal enuresis), referring to Amir Kabir Hospital. Setting and conduct: In this study, all the patients after obtaining informed consent, give a specific food recipes as well as Desmopressin spray will starts for disease, in addition said to parents that since the visit for a month in addition to the use of desmopressin spray, follow the recommended diet and record the number of nocturnal enuresis during these two months in a questionnaire which have placed for them. At the end the data were evaluated. Participants including major eligibility criteria: 180 children with primary nocturnal enuresis according to DSM-IV-TR criteria, without any underlying problem and do not have any chronic diseases were enrolled to study, and patients who refuse to cooperate were excluded. Intervention: Nutritional status evaluation and offering nutritional program. main outcome measures (variables): Nutritional status.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051213366N7**
Registration date: **2017-05-31, 1396/03/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-31, 1396/03/10

Registrant information

Name

Parsa Yousefi Chaijan

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Nutritional Factors in the Treatment of Primary Nocturnal Enuresis in Children

Public title

The Effect of Nutrition in the Treatment of Enuresis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: all children with primary nocturnal enuresis based on the criteria of DSM-IV-TR; without any underlying problem as secondary enuresis; did not have

a chronic disease! did not chronic consumption of any drugs. Exclusion criteria: Patients who are not willing to cooperate in the completing questionnaires! in the middle of the projects lake of their cooperation.

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Arak University of Medical Sciences

Street address

3848176941, Arak University of Medical Sciences, Sardasht, Arak.

City

Arak

Postal code

Approval date

2016-10-17, 1395/07/26

Ethics committee reference number

IR.ARAKMU.REC.1395.274

Health conditions studied

1

Description of health condition studied

Nocturnal Enuresis

ICD-10 code

F98.0

ICD-10 code description

A disorder characterized by involuntary voiding of urine at night.

Primary outcomes

1

Description

Nocturnal Enuresis

Timepoint

Since intervention for two months

Method of measurement

questionnaire filling

Secondary outcomes

empty

Intervention groups

1

Description

Follow the recommended diet. It is recommended that patients during the day consume vegetables, dried fruits, cereals and eggs. During the evening not consume yogurt, fruit juice, milk and cheese and reduce use of salt, chocolate, soft drinks, tea and juices.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

Parsa Yousefichaijan

Street address

3819693345, Amir Kabir Hospital, Basij Square, Arak.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, 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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Amir Kabir Hospital of Arak city

Full name of responsible person

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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Full name of responsible person

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Position

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