Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the efficacy of pharmacological and non-pharmacological therapy via group education on the control of primary nocturnal enuresis in school age children

Protocol summary

Summary

Study objective: To determine effectiveness of non-pharmacological and pharmacological treatment via group education on the control of primary nocturnal enuresis in school age children. This study is a randomized clinical trial. Inclusion criteria:at least 2 periods of enuresis per week for 3 consecutive months; Enuresis is not affected by mental and physical illness; Patients and families have not previously participated in the training groups. Exclusion criteria: Parents have no willingness to continue cooperation. not participate in at least one training session. The study population consisted of school children aged 6 to 12 years old with nocturnal enuresis and the sample size is 64. Study interventions included: non-pharmacological treatment intervention (group education), by the researcher on a group of 32 people and pharmacological treatment intervention, by a physician on a group of 32 people. Intervention period is three months. Before, during and after the intervention, the mean number of wet nights and the rate of improvement is evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102719702N1**
Registration date: **2014-12-06, 1393/09/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-12-06, 1393/09/15

Registrant information

Name

Sima Soroush

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61133738310

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences,Chronic Disease Care Research Center

Expected recruitment start date

2014-12-07, 1393/09/16

Expected recruitment end date

2015-02-05, 1393/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of pharmacological and non-pharmacological therapy via group education on the control of primary nocturnal enuresis in school age children

Public title

children enuresis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least 2 periods of enuresis per week for 3 consecutive months; Enuresis is not affected by

mental and physical illness; Patients and families have not previously participated in the training groups. Exclusion criteria: Parents have no willingness to continue cooperation; not participate in at least one training session.

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences

Street address
Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences,Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Alley, Ahvaz

City
ahvaz

Postal code
61357-15794

Approval date
2014-09-20, 1393/06/29

Ethics committee reference number
ajums.REC.1393.201

Health conditions studied

1

Description of health condition studied
nocturnal enuresis

ICD-10 code
F98.0

ICD-10 code description
Nonorganic enuresis

Primary outcomes

1

Description
control of nocturnal enuresis

Timepoint
Before intervention, First month, second month, third month, After intervention

Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Non-pharmacological therapy: parental education will be done, two educational group discussions sessions (sessions two weeks apart) will be held, in which parents will be divided into groups of 5-6 people. after completion of education check list for recording recommended daily activities for three months and educational booklet will be given to the parents

Category
Behavior

2

Description
Drug therapy group: Desmopressin tablets (120 microgr), once daily for 3 months is prescribed by a physician.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan hospital special clinic

Full name of responsible person
Sima Soroush

Street address
Golestan Hospital Special Clinic, Golestan Hospital, Golestan Avenue, Ahvaz

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ashraf alsadat Hakim

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Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Alley, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sima Soroush

Position

Master of Pediatric Nursing Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Educator

Other areas of specialty/work

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Other areas of specialty/work

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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