

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jul 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)

##### Phone

+98 61133738310

##### Email address

soroush.s@ajums.ac.ir

##### 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

**Street address**

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**

**Street address**

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**Position**

Educator

**Other areas of specialty/work**

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**Position**

Master of Pediatric Nursing student

**Other areas of specialty/work**

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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*