

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Compare of drug therapy (with oxibutinin, imipramine and desmopressin) with cognitive behavioral therapy to improve the rate of primary nocturnal enuresis in new school -aged children of education and training organization, referred to specialized clinics in 2014-2015

Protocol summary

Summary

The aim of this is to compare drug therapy (with oxibutinin, imipramine and desmopressin) with cognitive behavioral therapy to improve the rate of primary nocturnal enuresis. In this randomized double blind controlled clinical trial 45 children aged 7 to 12 years referred to doctor Hamid Ostadebrahimi's pediatric office for nocturnal enuresis will be assigned to receive oxibutinin, imipramine, desmopressin and behavioral therapy. Response to treatment will be assessed one, two, three and four months after the treatment. Inclusion criteria are to have primary nocturnal enuresis and being 7 to 12 years old. Exclusion criteria are to have neurogenic bladder, central nervous system disorders and secondary nocturnal enuresis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502091061N22**

Registration date: **2015-04-20, 1394/01/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-20, 1394/01/31

Registrant information

Name

Reza Vazirinejad

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 39 1822 0097

Email address

pejoheshi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare of drug therapy (with oxibutinin, imipramine and desmopressin) with cognitive behavioral therapy to improve the rate of primary nocturnal enuresis in new school -aged children of education and training organization, referred to specialized clinics in 2014-2015

Public title

Compare of drug therapy with cognitive behavioral therapy in improvement of enuresis in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion :to have primary nocturnal enuresis and being 7 to 12 years old , exclusion :to have neurogenic bladder, central nervous system disorders and secondary nocturnal enuresis

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Central Organization of Rafsanjan University of
Medical Sciences

Street address

Central Organization of Rafsanjan University of
Medical Sciences, Imam Ali Blvd, Rafsanjan

City

Rafsanjan

Postal code

7717933777

Approval date

2014-10-18, 1393/07/26

Ethics committee reference number

2017

Health conditions studied**1****Description of health condition studied**

Primary enuresis

ICD-10 code

F98.0

ICD-10 code description

Nonorganic enuresis

Primary outcomes**1****Description**

number of nocturnal enuresis

Timepoint

before the intervention

Method of measurement

olness questionnaire of nocturnal enuresis

Secondary outcomes**1****Description**

response to drug therapy (oxibutinin, imipramine and
desmopressin)

Timepoint

one, two, three and four months after the start of study

Method of measurement

olness questionnaire of nocturnal enuresis

2**Description**

response to cognitive behavioral therapy

Timepoint

one, two, three and four months after the start of
intervention

Method of measurement

olness questionnaire of nocturnal enuresis

Intervention groups**1****Description**

imipramine tablet (50mg)before sleep for one month,
oxibutinin tablet (5mg)two times a day for one month,
desmopressin spray (20micro g)intra nasal before sleep
for one month

Category

Treatment - Drugs

2**Description**

cognitive behavioral therapy by using of less drinking
before sleep, alarm clock wakes at night, enuresis alarm,
hypnosis, trying to remember to keep dry, parents wakes
at night, punishment for wet nights, rewards for dry
nights

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

pediatric office

Full name of responsible person

Drive,Hamid Ostadebrahimi

Street address

Rafsanjan after shohada junction, hakim clinic

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Esmaili Nadimi

Street address

Rafsanjan University of Medical Sciences, Rafsanjan

City

Rafsanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

*

Full name of responsible person

Hamid Ostadebrahimi

Position

Pediatrician /Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Central Organization of Rafsanjan University of Medical Sciences, Imam Ali Blvd, Rafsanjan

Full name of responsible person

Hamid Ostadebrahimi

Position

Pediatrician

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