

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of treatment of monosymptomatic nocturnal enuresis with combination of Desmopressin and Tolterodin versus Desmopressin alone

Protocol summary

Summary

The aim of this study is to compare treatment of monosymptomatic nocturnal enuresis with combination of Desmopressin and Tolterodin versus Desmopressin alone. The key inclusion criteria is be to have primary nocturnal enuresis and the key exclusion criteria are occurrence of side effects or missing the intake of more than two doses of the prescribed medication. One hundred patients with primary nocturnal enuresis from both genders aged between 5 to 16 referring to the urology clinic of Emam Reza hospital, Tabriz, Iran in a randomized unicentral double blinded clinical trial are assigned to receive Tolterodin 2 mg/day orally plus nasal Desmopressin 1 puff/night (two-drug regimen group) for 4 weeks or to receive nasal Desmopressin 1 puff/night and placebo (one-drug regimen group) with the same shape, size and color of the Tolterodin in a similar dose and duration. Individuals would be visited for occurrence of probable side effects and regularity of drug intake at the end of each week and number of nocturnal urination would be recorded to make comparison between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090610758N1**

Registration date: **2012-09-24, 1391/07/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-24, 1391/07/03

Registrant information

Name

Fahimeh Kazemi Rashed

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1658 4153

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-04-04, 1391/01/16

Expected recruitment end date

2012-10-06, 1391/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment of monosymptomatic nocturnal enuresis with combination of Desmopressin and Tolterodin versus Desmopressin alone

Public title

Comparison of two regimens in the treatment of nocturnal enuresis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (having primary nocturnal enuresis; not having secondary nocturnal risk factors such as urinary tract infection, constipation, Diabetes Mellitus, Diabetes Insipidus, obstruction of the urinary tract, neurogenic bladder and positive history of seizure; to be between 5

to 16 years old) Exclusion criteria: (having abnormal sonographic or urine analysis results; occurrence of side effects or missing the intake of more than two doses of the prescribed drugs)

Age

From **5 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz university of Medical Sciences

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Square

City

Tabriz

Postal code

Approval date

2011-10-05, 1390/07/13

Ethics committee reference number

9183

Health conditions studied

1

Description of health condition studied

Primary nocturnal enuresis

ICD-10 code

F98.0

ICD-10 code description

Nonorganic enuresis

Primary outcomes

1

Description

Frequency of nocturnal urination in a week

Timepoint

weekly for four weeks

Method of measurement

Using a questionnaire

Secondary outcomes

1

Description

Occurrence of side effects

Timepoint

Weekly for four weeks

Method of measurement

Physical examination by a specialist

Intervention groups

1

Description

In two-drug regimen group: Tolterodin 2 mg/day orally plus nasal Desmopressin 1 puff/night for 4 weeks

Category

Treatment - Drugs

2

Description

In one-drug regimen group: nasal Desmopressin 1 puff/night and placebo with the same shape, size and color of the Tolterodin once per night orally for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Fahimeh Kazemi Rashed

Street address

Emam Reza hospital, Golgasht ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences
Full name of responsible person
 Alireza Ostad Rahimi
Street address
 Vice chancellor for research, Tabriz University of
 Medical Sciences, Daneshgah Square
City
 Tabriz
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
 organization/entity?**
 Yes
Title of funding source
 Tabriz 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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