

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Comprasion of additive effect of solifenacin with tolterodine to desmopressin in treatment of children with primary nocturnal enuresis

#### Protocol summary

##### Study aim

Comparison of additive effect of solifenacin or tolterodine to desmopressin in treatment of children with primary nocturnal enuresis

##### Design

40 patients with primary nocturnal enuresis who has the inclusion criteria will be included. Patients will be randomly assigned to one of the two different therapeutic protocols and any participants will be given a specific code.

##### Settings and conduct

The study will be conducted in Urology clinic of Imam Khomeini hospital, Ahvaz, Iran. Patients were Randomly Selected. All participants will be evaluated monthly regarding treatment response and drug side effects for 6 months , after which the outcomes will be compared in both groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 5-15 years old children with primary nocturnal enuresis Exclusion criteria: Neurogenic bladder, CNS disorders and/or urine-concentrating defects

##### Intervention groups

Group A: Will take Intranasal Desmopressin spray 1 puff/night plus Tolterodine 1 mg tablet/oral/night Group B: Will take Intranasal Desmopressin spray 1 puff/night plus solifenacin 5 mg tablet/oral/night.

##### Main outcome variables

The main outcomes will be treatment response. Treatment response will be regarded as full response (complete dry), good response (90- 99% reduction in wet nights), or partial response (50- 90% reduction).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170509033894N3**

Registration date: **2018-01-31, 1396/11/11**

Registration timing: **retrospective**

Last update: **2018-01-31, 1396/11/11**

Update count: **0**

##### Registration date

2018-01-31, 1396/11/11

##### Registrant information

###### Name

Seyedeh parvin Mosavi ghanavati

###### Name of organization / entity

university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3445 2149

###### Email address

ghanavati.p@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research deputy, Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-12-22, 1396/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comprasion of additive effect of solifenacin with tolterodine to desmopressin in treatment of children with primary nocturnal enuresis

**Public title**

Comparison of two treatment method in children with primary nocturnal enuresis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

children with primary nocturnal enuresis

**Exclusion criteria:**

patients with neurogenic bladder CNS disorders urine-concentrating defects

**Age**

From **5 years** old to **15 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly (blocking method) divided into two groups

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Ahvaz, Golestan, Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Approval date**

2017-05-11, 1396/02/21

**Ethics committee reference number**

IR.AJUMS.REC.1396.72

**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**

Response to treatment

**Timepoint**

Monthly regarding during 6 months

**Method of measurement**

According things that their parents and children say, patients will be classified to full response (complete dry), good response (90 to 99% reduction in wet nights), and partial response (50 to 90% reduction).

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

Abdominal pain

**Timepoint**

Monthly during 6 months

**Method of measurement**

Clinical symptoms

**2****Description**

Vomiting

**Timepoint**

Monthly during 6 months

**Method of measurement**

Clinical symptoms

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

Intra nasal Desmopressin 1 puff/Qhs plus Tolterodine 1mg daily during 6 month

**Category**

Treatment - Drugs

**2****Description**

Intra nasal Desmopressin 1 puff/Qhs plus solifenacin 5 mg daily during 6 month

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Ahwaz Imam Khomeini hospital

**Full name of responsible person**

Seyede parvin mosavi ghanavati

**Street address**

Sharifezadeh ave.,24metry

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Ahwaz

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sp.mg90@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

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

**Full name of responsible person**

Mohammad Badavi

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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 and Technology of Ahvaz  
Jundishapur University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

## Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Seyedeh Parvin Mosavi Ghanavati

**Position**

Medical student

**Latest degree**

Bachelor

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Dinyar Khazaeli

**Position**

Urologist

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Specialist

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## Person responsible for updating data

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available