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
univercity

Country
Iran (Islamic Republic of)

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+98 61 3445 2149

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ghanavati.p@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source
Research deputy, Ahvaz Jundishapur Univercity 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 nucturnal enurises
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 intwo 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
Khouzestan
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
Seyedea parvin mosavi ghanavati

Street address
Sharifezadeh ave.,24metry

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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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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