

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of effects of Ritalin on giggle incontinence in children referring to Dr Sheikh hospital

Protocol summary

Study aim

Determination of effects of Ritalin on giggle incontinence in children referring to Dr Sheikh hospital

Design

In this study, all patients with giggle incontinence who refer to Nephrology Clinic, after being informed and acquisition of consent, will be included in the study.

Settings and conduct

Giggle incontinence is a type of incontinence in children that appears in the form of a little and sudden wetness which is unpredictable and is determined by unintentional depletion of bladder followed by giggling with normal function of bladder at other hours. This study is going to be carried out in Dr. Sheikh Hospital of Mashhad. There will be thorough neural and physical examination and assessment for all children. No blinding is done in the study. Finally after a month of drug use, patients will be evaluated from a medical response point of view. Medical response is then divided to 3 levels as following: 1-no response 2- relative response as reduction of incontinence numbers to half and 3- complete improvement.

Participants/Inclusion and exclusion criteria

All patients with giggle incontinence will be included in the study and children with neurologic urinary disorders, congenital anomalies and obstruction issues will be excluded.

Intervention groups

Intervention group: Patients are prescribed 0.2 milligram of Ritalin daily for one moth. It is recommended that the drug be given to children before going to school. Control group: Patients will be given Oxybutynin drug with dose of 0.1 milligram per kilogram. After a month, patients will be evaluated.

Main outcome variables

Rate of control and improvement of incontinence after use of Ritalin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111024007892N7**

Registration date: **2017-12-29, 1396/10/08**

Registration timing: **retrospective**

Last update: **2017-12-29, 1396/10/08**

Update count: **0**

Registration date

2017-12-29, 1396/10/08

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1606 1227

Email address

azarfara@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-11-19, 1393/08/28

Expected recruitment end date

2015-11-19, 1394/08/28

Actual recruitment start date

2014-11-19, 1393/08/28

Actual recruitment end date

2016-11-09, 1395/08/19

Trial completion date

empty

Scientific title

Investigation of effects of Ritalin on giggle incontinence in children referring to Dr Sheikh hospital

Public title

Investigation of effects of Ritalin on giggle incontinence in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

older than five years old patients with giggle incontinence completion of informed consent form no existence of urological diseases

Exclusion criteria:

patients with neurogenic bladder congenital disorders of urinary system urinary tract obstruction neurological disorders such as myelomenonucle unwillingness to participate in the study

Age

From **6 years** old to **12 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Using table of random numbers and envelope method, patients will be divided to two groups

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

No blinding is done.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Taheri Ave, Tohid Square, Dr. Sheikh Hospital,

City

Mashhad

Province

Razavi Khorasan

Postal code

1358- 91735

Approval date

2014-11-19, 1393/08/28

Ethics committee reference number

IR.MUMS.REC.1394.631

Health conditions studied

1

Description of health condition studied

urinary incontinence

ICD-10 code

R39.81

ICD-10 code description

Functional urinary incontinence

Primary outcomes

1

Description

Rate of control and improvement of incontinence after use of Ritalin

Timepoint

A month after use of Ritalin

Method of measurement

Medical response is divided to 3 levels as following: 1-no response 2- relative response as reduction of incontinence numbers to half and 3- complete improvement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients are prescribed 0.2 milligram of Ritalin daily for one moth. It is recommended that the drug be given to children before going to school

Category

Treatment - Drugs

2

Description

Control group: Patients will be given Oxybutynin drug with dose of 0.1 milligram per kilogram for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dr.Sheikh Hospital

Full name of responsible person

Anoosh Azarfar

Street address

Taheri Ave, Tohid Square, Dr. Sheikh Hospital

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Email

azarfara@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Mashhad University of Medical Sciences

Full name of responsible person

Anoosh Azarfar

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Anoosh Azarfar

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments