Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of oral midazolam on tension of children with urinary tract defects during voiding cystourethrography

Protocol summary

Summary

In this survey we want to study the effects of oral midazolam on tension of children with urinary tract defects during voiding cystourethrography. The key inclusion criteria is to be older than 3 years old the key exclusion criteria is unwillingness of the parents to continue the study. 84 patients with urinary tract defects who are candidate for voiding cystourethrography referring to Tabriz Children's hospital, Tabriz, Iran will be involved and divided into two equal sized groups. In the intervention group children will receive 50mg/kg oral midazolam half an hour before VCUG, and the tension and stress level during the VCUG will be observed and recorded by a nephrologist. Then the patients would be evaluated in terms of voiding dysfunction by the same person. All mentioned measures will be performed for the nonintervention group as well except for the administration of midazolam. Then all the gathered data will be compared between the groups to draw a onclusion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110257892N2**
Registration date: **2012-08-09, 1391/05/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-09, 1391/05/19

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-06-22, 1391/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of oral midazolam on tension of children with urinary tract defects during voiding cystourethrography

Public title

The effects of midazolam on voiding cystogram quality

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria : (to be 3 to 12 years old) Exclusion criteria : (unwillingness of the parents to continue the study)

Age

From **3 years** old to **12 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Tabriz University of medical sciences
Street address
Deputy of resarch,Faculty of medeicne, Tabriz ,East Azarbaujan,Iran
City
Tabriz
Postal code
Approval date
2011-01-22, 1389/11/02
Ethics committee reference number
5/4/8674

Health conditions studied

1

Description of health condition studied
Urinary system disorders
ICD-10 code
N39.9
ICD-10 code description
Disorder of urinary system, unspecified

Primary outcomes

1

Description
Stress level
Timepoint
During the cytography
Method of measurement
Observaion and recording in the questionnaire

2

Description
Voiding dysfunction
Timepoint
During the cystograpy
Method of measurement
Observation by a nephrologist

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group: half an hour before the cystoggraphy Midazolam 50 mg/kg will be administered orally.
Category
Treatment - Drugs

2

Description
In nonintervention group the cyctography will be performed without administeration of Midazolam.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children's Hospital
Full name of responsible person
Majid Malaki
Street address
Children's hospital, Sheshgelan st.
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
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Majid Malaki
Position
Subspecialist in children's nephrology/Assistant professor
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
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Mehdi Hemmati
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General physician
Other areas of specialty/work
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Postal code
Phone
Fax
Email
Mehdi.hemmati@rocketmail.com
Web page address

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