

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 conclusion.

#### 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)

##### Phone

+98 51 1606 1227

##### Email address

azarfara@mums.ac.ir

##### 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 medicine, 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

Observation and recording in the questionnaire

### 2

#### Description

Voiding dysfunction

#### Timepoint

During the cystography

#### Method of measurement

Observation by a nephrologist

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In intervention group: half an hour before the cystography Midazolam 50 mg/kg will be administered orally.

#### Category

Treatment - Drugs

### 2

#### Description

In nonintervention group the cystography will be performed without administration 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

**Other areas of specialty/work**

**Street address**

Children's Hospital, Sheshgelan st.

**City**

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+98 41 1526 2261

**Fax**

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Anush Azarfar

**Position**

Assistant professor, subspecialist in children's

nephrology

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Hemmati

**Position**

General physician

**Other areas of specialty/work**

**Street address**

Emam Reza hospital, Golgasht avenue

**City**

Tabriz

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**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*