Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Review and Comparison of sedative effect in using of chloral hydrate and midazolam on children under voiding cystourethrogram

Protocol summary

Summary

Since VCUG is an offensive method that is unpleasant and stressful to children and parents. The aim of this study was to compare the effects of injection Midazolam and oral Chloral hydrate for decreasing stress and increasing cooperating children in VCUG. For this purpose among referral patients from nephrologist to Amir Kabir hospital 150 children selected randomly and divided to three groups. Initially 30 minuets before test midazolam was injected to first group, oral Chloral hydrate was given to second group and was not given drugs to third group. Unlike routine VCUG process that not use of sedation, in this study two above drugs were used. Then a questionnaire to measure the child's cooperation during the test, ease of separation of children from parents, residual urinary volume and adverse drug reactions by resident based on observations of children's behavior during testing project was completed and the results of groups were compared and investigated. In the following the conditions of study are mentioned: Entrance general conditions to Study including: children from 2-12 years old both male & female؛ Children with indication VCUG؛ children with ASA 1 or 2؛ obtaining the informed consent from parents or guardian of children To participate in the study and Exclusion general conditions from Study including: History of systemic chronic diseases such as Renal failure, Respiratory disease and etc؛ history of narcotic abuse؛ history sensitivity to midazolam or chloral hydrate؛ history chronic psychiatric disease including: ADHA, Anxiety, Depression, psychos and Metal retardation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041927494N1**

Registration date: **2017-03-04, 1395/12/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name

Mahdi Aghagoli

Name of organization / entity

Arak Medical University

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Medical university of ARAK

Expected recruitment start date

2016-02-16, 1394/11/27

Expected recruitment end date

2017-02-15, 1395/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Review and Comparison of sedative effect in using of chloral hydrate and midazolam on children under voiding cystourethrogram

Public title

Review and Comparison of sedative effect in using of chloral hydrate and midazolam on children under voiding cystourethrogram

Purpose

Supportive

Inclusion/Exclusion criteria

Entrance general conditions to Study: children from 2 - 12 years old both male & female؛ Children with indication VCUG؛ children with ASA 1 or 2؛ obtaining the informed consent from parents or guardian of children To participate in the study Exclusion general conditions from Study: History of systemic chronic diseases such as Renal failure, Respiratory disease and etc؛ history of narcotic abuse؛ history sensitivity to midazolam or chloral hydrate؛ history chronic psychiatric disease including: ADHA, Anxiety, Depression, psychos and Metal retardation.

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak Medical University

Street address

Enghelab Square

City

Arak Medical University, Sardasht St, Enghelab Sq, Arak

Postal code

Approval date

2016-02-15, 1394/11/26

Ethics committee reference number

IR.ARAKMU.REC.1394.318

Health conditions studied

1

Description of health condition studied

Vesico uretro reflux

ICD-10 code

Q62.7 , N

ICD-10 code description

Congenital vesico-uretero-renal reflux

Primary outcomes

1

Description

Sedation

Timepoint

On time with study

Method of measurement

Visit & question from parents

Secondary outcomes

empty

Intervention groups

1

Description

Without Drug

Category

Treatment - Drugs

2

Description

Chloralhydrate 0/5 cc/kg. Oral. Singledose

Category

Treatment - Drugs

3

Description

Midazolam 100/150 mcg/kg. IM. single dosel

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Safi sonography clinic

Full name of responsible person

Dr.Safi

Street address

Floor 9, Amirkabir medical complex, Shariati Sq, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Dr.Rafiee
Street address
Arak Medical University, Technology and Research department of Payambar azam university
City
Arak
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, Arak 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
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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