Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of atracurium on the ease of hernia surgery in children in compare with routine care

Protocol summary

Study aim

Evaluation of the effect of atracurium on the ease of hernia surgery in children

Design

This study is a randomized clinical trial with two parallel groups (intervention group 30 and control group 30). In this study, 60 patients with unilateral inguinal hernia with the inclusion criteria were randomly divided into intervention and control groups and each participant was assigned a code. Each group will receive its own intervention.

Settings and conduct

This study will be performed on children with a unilateral inguinal hernia. The study setting is Sheikh Hospital affiliated with Mashhad University of Medical Sciences. Patients with inclusion criteria are divided into two group using randomized assignment. In the intervention group, patients receive 0.3 mg/kg of atracurium, while the control group does not receive this intervention. In this double-blinded study, the investigator and patients are blinded.

Participants/Inclusion and exclusion criteria

All children (over 6 months and under 7 years of age) without underlying illness (collagen vasculature, altoegropenia), who undergo a selective surgical procedure for the repair of a one-sided and indirect hernia. Children with the previous history of sensitization to Atracurium will not be included in the study.

Intervention groups

In both groups, anesthetist, surgeon, and anesthetist are the same. In the intervention group, patients receive 0.3 mg / kg atracurium, while the control group does not receive this intervention. This drug is injected by a third person who is not aware of the study process.

Main outcome variables

The primary outcome is the surgeon's ease to see the hernial sac which is measured in three grades.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170829035978N1**
Registration date: **2018-01-19, 1396/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-19, 1396/10/29**
Update count: **0**

Registration date

2018-01-19, 1396/10/29

Registrant information

Name

Sahar Ahmadi Bonakdar

Name of organization / entity

MUMS

Country

Iran (Islamic Republic of)

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+98 51 3852 5209

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial of the effect of atracurium on the ease of hernia surgery in children in compare with routine care

Public title
The effect of atracurium on the ease of hernial surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with a minimum of 6 months and a maximum of 7 years of age Children with an inguinal hernia undergo elective surgery for a unilateral and indirect hernia Children without underlying illness (collagen vasculature, altoprgenegna)
Exclusion criteria:
Having a history of allergy to atracurium Renal Failure Hepatic Failure
Age
From **6 months** old to **7 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who met the inclusion criteria were randomly assigned to two groups of control and intervention using a random numbers table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are unaware of the type of intervention due to anesthesia. The researcher was unaware of the allocation of the two intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: Patients were assigned to the intervention and control group using random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad university of medical sciences
Street address
Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2016-08-05, 1395/05/15
Ethics committee reference number
IR.MUMS.fm.REC.1395.522

Health conditions studied

1

Description of health condition studied
Inguinal Hernia
ICD-10 code
K40
ICD-10 code description
Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description
The ease of the surgeon in seeing the hernia sac
Timepoint
post intervention
Method of measurement
Grading the surgeon satisfaction by researcher constracted scale based on three grades: (1) Easily accessible and found with the first attempt. (2) The hernia sack is not easily found and two or three attempts to find the sack are necessary (3) The sack is hard to find and gets torn when the sack is found.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of Atracurium 0.3 mg/kg simultaneously with induction of anesthesia.
Category
Treatment - Drugs

2

Description
Control group: Routine intervention that is performed

during all children's inguinal hernia surgery. The injection of atracurium is not routinely used in these surgeries.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sheikh Hospital

Full name of responsible person

Sahar Ahmadi Bonakdar

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Tohid Square, Taheri St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vice chancellor for research

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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

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

Sahar Ahmadi

Position

MD

Latest degree

Medical doctor

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable