

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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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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 constructed 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

empty

Country of origin

Type of organization providing the funding

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sheikh Hospital

Full name of responsible person

Sahar Ahmadi Bonakdar

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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

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

Anesthesiology

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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