

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Acetaminophen on hemodynamic changes during intubation in children undergoing hypospadias surgery

Protocol summary

Study aim

Determination of the effect of Acetaminophen on hemodynamic changes during intubation in children undergoing hypospadias surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 126 patients. R-statistical software is used for block randomization.

Settings and conduct

The present study will be performed in Bahonar Hospital in Kerman. After the patient enters the operating room, systolic blood pressure, diastolic blood pressure and heart rate are checked and recorded before induction of anesthesia, after induction of anesthesia and at 1, 3, 6 and 9 minutes after intubation with the patient monitoring system. After the operation, incidence of nausea and vomiting during the recovery and 6 hours after leaving the recovery is assessed by asking the child or parents of the child. In order to double-blind the study, patients and the person responsible for data collection are unaware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include children undergoing hypospadias surgery aged 2 to 7 years. Exclusion criteria included known allergy to Acetaminophen, renal or hepatic impairment, bleeding disorders, history of known cardiovascular or respiratory disease, history of seizures, neurological or neuromuscular disorders, History of chronic pain or use of pain medication, and also Predict hard intubation

Intervention groups

In the intervention group, children received 15 mg / kg suppository Acetaminophen two hours before surgery, and in the control group, children did not receive Acetaminophen suppositories.

Main outcome variables

Reduce blood pressure fluctuations and heart rate during surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101220005426N10**

Registration date: **2021-08-18, 1400/05/27**

Registration timing: **prospective**

Last update: **2021-08-18, 1400/05/27**

Update count: **0**

Registration date

2021-08-18, 1400/05/27

Registrant information

Name

Mehdi Ahmadinejad

Name of organization / entity

Anesthesiology department, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Acetaminophen on hemodynamic changes during intubation in children undergoing hypospadias surgery

Public title

Effect of Acetaminophen on hemodynamic changes during intubation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children undergoing hypospadias surgery Children aged 2 to 7 years

Exclusion criteria:

Known allergy to Acetaminophen Renal or hepatic impairment Bleeding disorders History of known heart or respiratory disease History of seizures Neurological or neuromuscular disorders History of chronic pain or use of pain medication Predict hard intubation

Age

From **2 years** old to **7 years** old

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is used to randomize people into two groups. In this way, quadruple blocks are used. In each quadruple blocks, 2 people are assigned to group A (intervention group) and 2 people to group B (control group); So we have six quadruple blocks consisting of AABB, ABAB, BBAA, BABA, ABBA, BAAB. From the blocks, one is first selected at random and according to its order, the samples are assigned to two groups (for example, if the BBAA block is selected, the first two patients are assigned to group B and the next two patients to group A). R statistical software is used for random block allocation. Unit of randomization is individual.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to double-blind the study, patients and the person responsible for data collection are unaware of the intervention. Patients are unaware of the type of intervention and the group in which they are due to their young age. Also, the person in charge of data collection who performs all data recording operations and question from the patient or the patient's companion is also unaware of the intervention and the group in which the patient is.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jihad Blvd, Somayye Crossroads, Shariaati St, Kerman

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2021-05-03, 1400/02/13

Ethics committee reference number

IR.KMU.REC.1400.105

Health conditions studied**1****Description of health condition studied**

Intubation

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

2**Description of health condition studied**

Hypospadias

ICD-10 code

Q54

ICD-10 code description

Hypospadias

Primary outcomes**1****Description**

Systolic blood pressure

Timepoint

Checking of systolic blood pressure before induction of anesthesia, after induction of anesthesia and at 1, 3, 6 and 9 minutes after intubation

Method of measurement

Patient monitoring system

2

Description

Diastolic blood pressure

Timepoint

Checking of diastolic blood pressure before induction of anesthesia, after induction of anesthesia and at 1, 3, 6 and 9 minutes after intubation

Method of measurement

Patient monitoring system

3

Description

Heart rate

Timepoint

Checking of heart rate before induction of anesthesia, after induction of anesthesia and at 1, 3, 6 and 9 minutes after intubation

Method of measurement

Patient monitoring system

4

Description

Incidence of nausea and vomiting

Timepoint

Evaluation of nausea and vomiting during recovery and 6 hours after recovery

Method of measurement

Ask the child or parents of the child

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving Acetaminophen suppository at a dose of 15 mg per kg body weight of the child once rectally two hours before surgery (before intubation)

Category

Rehabilitation

2

Description

Control group: Children do not take Acetaminophen suppositories

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital, Kerman

Full name of responsible person

Mehdi Ahmadinejad

Street address

Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ahmadinejad

Position

Assistant Professor- Fellow of Intensive Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Position Assistant Professor- Fellow of Intensive Care

Latest degree

Specialist

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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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