Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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, Jahad Blvd, Somayye Crossroads, Shariaati St, Kerman
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Kerman
Province
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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
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Sponsors / Funding sources

1

Sponsor
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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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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