

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of paracetamol ampoule and acetaminophen suppository on postoperative pain control in children admitted to pediatric surgery department

Protocol summary

Study aim

Comparison of the effects of paracetamol ampoule and acetaminophen suppository in postoperative pain in children admitted to the pediatric surgery ward

Design

A clinical trial is implemented with two intervention groups (paracetamol and acetaminophen suppository), with parallel groups, single blind, randomized, and is performed on 70 children (35 children in the paracetamol group) and (35 children in the acetaminophen suppository group). Lottery is used for randomization.

Settings and conduct

The intervention is implemented in the pediatric surgery ward of Imam Ali Hospital in Zahedan, Iran. The intervention is performed on 70 children by simple random sampling. This research is performed as single-blind. In such a way that the co-researcher is not known, what kind of medicine (intervention) has been done for the child.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being candidate for abdominal surgery; no history of surgery in 1 recent year; do not received analgesic drug in the last 4 hours; no history of allergy to acetaminophen. Exclusion criteria: complications such as diarrhea, vomiting, throat, severe headache.

Intervention groups

In the acetaminophen suppository group, the child's pain is assessed before the intervention. Acetaminophen suppositories (125 mg) are inserted into the baby's anus. One hour and 2 hours after the intervention, the pain is recorded again. In the paracetamol ampoule group, the child's pain is examined before the intervention. Paracetamol ampoule infused with 100 cc of 0.9% normal saline for 15 minutes. 1 hour and 2 hours after the intervention, the child's pain is re-recorded.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121025011261N4**

Registration date: **2021-03-02, 1399/12/12**

Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**

Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

Alia Jalalodini

Name of organization / entity

Nursing and Midwifery College

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 2481

Email address

jalalodini@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Ethics committee of Zahedan University of Medical Sciences
Scientific title	Street address
The effect of paracetamol ampoule and acetaminophen suppository on postoperative pain control in children admitted to pediatric surgery department	Zahedan University of Medical Sciences, Janat Blvd.
Public title	City
The effect of paracetamol ampoule and acetaminophen suppository on postoperative pain control	Zahedan
Purpose	Province
Treatment	Sistan-va-Balouchestan
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	9816745477
Being candidate for surgery on the abdominal organ.	Approval date
Having the order of paracetamol ampoule and acetaminophen suppository as PRN on the patient file by physician. Have not history of acetaminophen allergy. Do not received analgesic drug in the last 4 hours.	2021-02-14, 1399/11/26
Exclusion criteria:	Ethics committee reference number
Having complications such as diarrhea, vomiting, throat, and severe headache Not collaborating of child or family	IR.ZAUMS.REC.1399.493
Age	Health conditions studied
From 1 year old to 6 years old	<u>1</u>
Gender	Description of health condition studied
Both	Pain
Phase	ICD-10 code
2-3	G89.1
Groups that have been masked	ICD-10 code description
Care provider	Acute pain, not elsewhere classified
Sample size	Primary outcomes
Target sample size: 70	<u>1</u>
Randomization (investigator's opinion)	Description
Randomized	Pain
Randomization description	Timepoint
Samples divided randomly into two groups. As, we consider a code or number for each of the samples. Then, by lottery method, the samples will be assigned to two groups; paracetamol and acetaminophen suppositories.	1 hour and 2 hours after receiving analgesia medicine
Blinding (investigator's opinion)	Method of measurement
Single blinded	Toddler -preschooler postoperative pain scale
Blinding description	Secondary outcomes
The co- researcher not know what kind of medicine (intervention) has been accomplished for the child.	empty
Placebo	Intervention groups
Not used	<u>1</u>
Assignment	Description
Parallel	Intervention group (1): in the group of acetaminophen suppository, the intensity of the child's pain is evaluated before the intervention. Then, according to the physician's order (PRN and based on weight), acetaminophen suppository (125 mg) is placed in the child's anal area with co-researcher.1 hour and 2 hours after acetaminophen suppository, the child's pain is examined and the pain score is recorded.
Other design features	Category
	Treatment - Drugs
Secondary Ids	<u>2</u>
empty	Description
Ethics committees	Intervention group (2): in the paracetamol ampoule group, the child's pain intensity is examined before the
<u>1</u>	
Ethics committee	
Name of ethics committee	

intervention. After investigating the physician's order (PRN) and examining the dose of paracetamol ampoules (based on weight), the co-researcher mixes the ampoule with 100 cc of 0.9% normal saline and infused for 15 minutes. 1 hour and 2 hours after paracetamol injection, the child's pain intensity is re-evaluated and the pain score is recorded.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Abne Abitaleb Hospital related to Zahedan
University of Medical Sciences and Health Services

Full name of responsible person

Alia Jalalodini

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Ali Abne Abitaleb Hospital, Health Blvd, Persian Gulf
Highway, Zahedan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Normohammad Bakhshany

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Zahedan University of Medical Sciences, Janat Blvd

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Alia Jalalodini

Position

Faculty member of science, Master of science in
nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Phone**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