Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of ropivacaine in transverse abdominis plane (TAP) block for pain in pediatrics undergoing appendectomy : a controlled randomized trial

Protocol summary

Study aim

Investigating the effect of Ropivacaine in TAP block in reducing analgesic consumption and pain reduction after appendectomy in children

Design

The study of a clinical trial has a control group with parallel, double-blind, randomized, block-based groups on 50 patients. Candidates in this study were randomly divided into 2 groups in the form of blocks of 4 with equal volume. First 12 blocks of 4 are prepared (Excel software is used to prepare random arrangements inside each block) and then these blocks are arranged randomly and people are assigned to two groups according to A and B are given. In order to hide the allocation process, closed envelopes will be used.

Settings and conduct

Patients who candidate for appendectomy at AKBAR hospital after parents consent will participated in study. Data analysts and patients were blinded to which group they entered.To hide the allocation process, closed envelopes will be used.

Participants/Inclusion and exclusion criteria

Age 4 -16 years Patient who candidate for appendectomy

Intervention groups

All patients are first administered intravenous ketamine at a dose of 1.5 milligrams per kilogram in the waiting room before being transferred to the operating room. Patients receive sevoflurane 6% along with remifentanil at a dose of 0.6 mic/kg and rocuronium at a dose of 0.6 mg/kg intravenously, prior to endotracheal intubation. General anesthesia is maintained with the minimal alveolar concentration of sevoflurane and an infusion of remifentanil at a rate of 0.05 mic/kg/min. In the intervention group, TAP block is performed using 0.2% ropivacaine at a dose of 0.5 milliliters per kilogram, guided by ultrasound at the end of the surgery and before the patient awakens from general anesthesia. All standard pain management protocols are uniformly applied to both groups postoperatively.

Main outcome variables

Pain after surgery Amount of morphine consumed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230315057725N1**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-05, 1402/06/14**
Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Mohadeseh Sabour Darbandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3864 8137

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of ropivacaine in transverse abdominis plane (TAP) block for pain in pediatrics undergoing appendectomy : a controlled randomized trial

Public title

Evaluation of the efficacy of transverse abdominis plane (TAP) block for pain in pediatrics undergoing appendectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient who candidate for appendectomy Age between 4 to 16 years old Obtaining informed consent from parents to participate the study

Exclusion criteria:

Having other comorbidities History of previous surgery Candidate for performing several operations at the same time Abnormal laboratory data High body mass index Perforated appendicitis Allergic reaction to local anesthetics

Age

From **4 years** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is used. Candidates in this study were randomly divided into 2 groups in the form of blocks of 4 with equal volume. For this purpose, first 12 blocks of 4 are prepared (Excel software is used to prepare random arrangements inside each block) and then these blocks are arranged randomly and people are assigned to two groups according to A and B are given This action continues continuously until the sample volume is completed. Also, in order to hide the allocation process, closed envelopes will be used

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants enter the study after obtaining consent and receiving explanations from two study groups. However, the decision about which group they will participate in will be blinded. Additionally, the assessors who evaluate postoperative pain at specified time intervals will be blinded to whether the patient has been enrolled in either of the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Medicine, Mashhad University of Medical Sciences (Research Ethics Committee)

Street address

No 63, 14 Daneshjou Ave, Daneshjou Boulevar, Mashhadd

City

Mashhad

Province

Razavi Khorasan

Postal code

9188961441

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.035

Health conditions studied

1

Description of health condition studied

Pain after appendectomy

ICD-10 code

Y48.02

ICD-10 code description

local anesthetics

Primary outcomes

1

Description

Pain after surgery

Timepoint

Every 4 hours till 12 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The total amount of analgesics consumption

Timepoint

12 hours after surgery

Method of measurement

The total dose of morphine consumption

Intervention groups

1

Description

All patients are first administered intravenous ketamine at a dose of 1.5 milligrams per kilogram in the waiting room to achieve tranquility before being transferred to the operating room. Subsequently, patients receive sevoflurane 6% along with remifentanil at a dose of 0.6 micrograms per kilogram and rocuronium at a dose of 0.6 milligrams per kilogram intravenously, prior to endotracheal intubation. General anesthesia is maintained with the minimal alveolar concentration of sevoflurane and an infusion of remifentanil at a rate of 0.05 micrograms per kilogram per minute.In the intervention group, tap block is performed using 0.2% ropivacaine at a dose of 0.5 milliliters per kilogram, guided by ultrasound at the end of the surgery and before the patient awakens from general anesthesia. All standard pain management protocols are uniformly applied to both groups postoperatively.

Category

Treatment - Other

2

Description

All patients are first administered intravenous ketamine at a dose of 1.5 milligrams per kilogram in the preoperative waiting room to achieve tranquility before being transferred to the operating room. Subsequently, patients receive sevoflurane 6% along with remifentanil at a dose of 0.6 micrograms per kilogram and rocuronium at a dose of 0.6 milligrams per kilogram intravenously, prior to endotracheal intubation. General anesthesia is maintained with the minimal alveolar concentration of sevoflurane and an infusion of remifentanil at a rate of 0.05 micrograms per kilogram per minute.. It's important to note that all standard pain management protocols are uniformly applied to both groups postoperatively.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar hospital

Full name of responsible person

Mohadeseh Sabour Darbandi

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No 63, 14 Daneshjou Ave, Daneshjou Boulevar, Mashhadd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ebrahim Golmakani

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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

Mohadeseh Sabour Darbandi

Position

Resident

Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available