# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

12 Jun 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)

**Phone**

+98 51 3864 8137

**Email address**

sabourm991@mums.ac.ir

**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

**Street address**

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sabourm991@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ebrahim Golmakani

**Street address**

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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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**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**
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