

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of intravenous dexamethasone and intravenous acetaminophen (apotel) on postoperative pain and agitation of 2-6-year-old children undergoing general anesthesia for dental rehabilitation

Protocol summary

Study aim

Comparison of intravenous dexamethasone and intravenous acetaminophen (apotel) on postoperative pain and agitation of 2-6-year-old children undergoing general anesthesia for dental rehabilitation

Design

This clinical trial included a control group with parallel groups, was double-blind, and randomized on 40 patients. Randomization is simple by a table of random numbers. Each vial is randomly selected based on the envelope randomization process, and an operating room nurse who is not a member of the research team selects the drugs that will be used.

Settings and conduct

This study will be performed on children aged 2 to 6 years referred to the pediatric ward of Tehran UMS who are candidates for general anesthesia for treatment. Patients were randomly divided into two equal groups and received intravenous dexamethasone and intravenous acetaminophen 15-30 minutes before the end of anesthesia. After completing the dental work within the first 30 minutes after recovery and discharge time, patients' pain is recorded using the CHEOPS criterion, nausea and vomiting, sore throat, and agitation are recorded according to the PAED criterion. This study is double-blind and the outcome evaluator and participant are not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion: Children 2 to 6 years old are candidates for general anesthesia for dental rehabilitation. Children with ASA I, II status. Consent of the child and parents to participate in the study Exclusion: Patients need a tooth extraction. Patients with a history of chronic systemic diseases. Patients with a history of allergies to any of the drugs used in the study. Patients with a history of respiratory problems, allergies, motor, and mental illness.

Intervention groups

Children 2 to 6 years old are candidates for general anesthesia for dental rehabilitation

Main outcome variables

Pain and agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220107053654N1**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Maryam Khosrozadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous dexamethasone and intravenous acetaminophen (apotel) on postoperative pain and agitation of 2-6-year-old children undergoing general anesthesia for dental rehabilitation

Public title

The effect of intravenous dexamethasone and acetaminophen on postoperative pain and agitation children undergoing general anesthesia for dental rehabilitation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 2 to 6 years old are candidates for general anesthesia for dental rehabilitation Children with ASA I, II status Consent of the child and the child's parents to participate in the study

Exclusion criteria:

Patients need a tooth extraction Patients with a history of chronic systemic diseases Patients with a history of allergies to any of the drugs used in the study Patients with a history of respiratory problems, allergies, motor, and mental illness

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple and its unit is the individual. Randomizing the table of random numbers is our tool. Patients will be randomly assigned treatment types. In this way, each vial is randomly selected based on the envelope randomization process, and an operating room nurse who is not a member of the research team selects the drugs that will be used. Due to this, neither the patient nor the researcher is aware of the type of treatment chosen, ensuring blindness in the bilateral study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is double-blind. For blinding the contents of the vials will be specified with the code A

(intravenous dexamethasone) and B (Apotel), and will be placed inside sealed envelopes (envelope); An operating room nurse who is not a member of the research team randomly selects the drugs used. The nurse registers the variables at the end of the operation and participants are blind to the content of the syringes used.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Central office of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.172

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

The amount of pain after dental treatment under general anesthesia

ICD-10 code

Z48.814

ICD-10 code description

Encounter for surgical aftercare following surgery on the teeth or oral cavity

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

Pain measurement

Timepoint

During the first 30 minutes after recovery, discharge time, 24 hours after discharge

Method of measurement

Children's hospital of eastern Ontario pain score:

CHEOPS

2

Description

Nausea and vomiting

Timepoint

During the first 30 minutes after recovery, discharge time, 24 hours after discharge

Method of measurement

Checklist: its presence / absence

3

Description

Sore throat

Timepoint

During the first 30 minutes after recovery, discharge time, 24 hours after discharge

Method of measurement

Checklist: Mild / Medium / Severe

4

Description

Agitation

Timepoint

During the first 30 minutes after recovery, discharge time, 24 hours after discharge

Method of measurement

PAED score (pediatric agitation emergence delirium score)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 20 children aged 2-6 years referred to the pediatric ward of Tehran University of Medical Sciences who are candidates for dental treatment under general anesthesia. These patients receive intravenous dexamethasone 0.5 mg/kg immediately after induction after obtaining informed consent and preparing the patient for treatment under anesthesia. Except for fentanyl used at the beginning of anesthesia, no opioid analgesics NSAIDs, or antiemetics are used 24 hours before and during the operation, and none of the patients receive local anesthesia before dental interventions. At the end of the operation, after the patient returns to breathing, the reverse of the neuromuscular block is slowly injected and the patient is extruded while awake. Treatment is performed and within the first 30 minutes after recovery as well as the time of discharge, pain, nausea, and vomiting in the presence/absence of it, mild/moderate/severe sore throat and agitation are evaluated and recorded by a trained nurse. During telephone calls with parents within 24 hours after discharge, the presence of sore throat

nausea, and vomiting are recorded again.

Category

N/A

2

Description

Intervention group 2: 20 children aged 2-6 years referred to the pediatric ward of Tehran University of Medical Sciences who are candidates for dental treatment under general anesthesia. After obtaining informed consent and preparing the patient for treatment under anesthesia, these patients receive 15 mg/kg of Apotel in ten minutes in the last 15 minutes. During the treatment, except for fentanyl used at the beginning of anesthesia, no opioid analgesics NSAIDs, or anti-nausea is used in the 24 hours before and during the operation, and none of the patients receive local anesthesia before dental interventions. At the end of the operation, after the patient returns to breathing, the reverse of the neuromuscular block is slowly injected and the patient is extruded while awake. Within the first 30 minutes after recovery, as well as the time of discharge, pain, nausea, and vomiting in the presence/absence of it, mild/moderate/severe sore throat and agitation are assessed and recorded by a trained nurse. During telephone calls with parents within 24 hours after discharge, the presence of sore throat nausea, and vomiting are recorded again.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, School of Dentistry, Tehran University of Medical Sciences and Health Se

Full name of responsible person

Saeide Mokhtari Khoei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Saeide Mokhtari Khoei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

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