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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+98 21 4279 4000

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khosrozadeh.mm@gmail.com

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
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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
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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