

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the Effect of Caffeine Citrate with Placebo on the Wake-Up Rate of Children 12-36 months After Outpatient Surgery under General Anesthesia with Inhaled Anesthetics

Protocol summary

Study aim

Comparison of the Effect of Caffeine Citrate with Placebo on the Wake-Up Rate of Children 12-36 months After Outpatient Surgery under General Anesthesia with Inhaled Anesthetics

Design

Double blind randomized clinical trial.

Settings and conduct

sevfluorine is discontinued in the suturing process and 20 cc syringes containing 10 mg / kg of caffeine citrate diluted with distilled water will be administered to the patients in the intervention group. Control group: In the control group, 20 cc of distilled water were received in 20cc syringe.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 12 to 36 months, (ASA I), Duration of surgery less than one hour. Exclusion criteria: history of seizure. Heart rate > 150., asthma, airway irritability, heart disease, hyperactivity, cerebrovascular accidents, obstructive sleep apnea, emergency, surgery, rising ETco2> 40 mmHg, Unsuccessful ventilation with laryngeal mask.

Intervention groups

sevfluorine is discontinued in the suturing process and 20 cc syringes containing 10 mg / kg of caffeine citrate diluted with distilled water will be administered to the patients in the intervention group. Control group: In the control group, 20 cc of distilled water were received in 20cc syringe.

Main outcome variables

Emergence, Systolic blood pressure, diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190511043550N1**

Registration date: **2019-05-13, 1398/02/23**

Registration timing: **prospective**

Last update: **2019-05-13, 1398/02/23**

Update count: **0**

Registration date

2019-05-13, 1398/02/23

Registrant information

Name

Ashkan Panah

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

Email address

panah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-12, 1398/03/22

Expected recruitment end date

2019-09-13, 1398/06/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Caffeine Citrate with Placebo on the Wake-Up Rate of Children 12-36 months After

Outpatient Surgery under General Anesthesia with Inhaled Anesthetics

Public title

Comparison of the Effect of Caffeine Citrate with Placebo on the Wake-Up Rate of Children 12-36 months After Outpatient Surgery under General Anesthesia with Inhaled Anesthetics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 12 to 36 months (ASA I) Duration of surgery less than one hour

Exclusion criteria:

History of seizure Heart rate > 150 Asthma Airway irritability Heart disease Hyperactivity Cerebrovascular accidents Obstructive sleep apnea Emergency surgeries Unsuccessful ventilation with laryngeal mask. Rising ETco2> 40 mmHg, Common cold

Age

From **12 months** old to **36 months** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be based on the randomization table, which is derived from www.randomization.org.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the intervention group: 20 cc syringe containing caffeine citrate with a dose of 10 mg per kg diluted with distilled water is prepared and supplied to the researcher by a person who is unaware of the study phases and will be administered to the patients in the intervention group. In the control group, a syringe of the same size as the intervention group (containing 20 cc distilled water) is provided by a person who is unaware of the study groups and provided to the researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-04-09, 1398/01/20

Ethics committee reference number

IR.SUMS.MED.REC.1398.080

Health conditions studied

1

Description of health condition studied

Emergence

ICD-10 code

F13

ICD-10 code description

Sedative, hypnotic, or anxiolytic related disorders

Primary outcomes

1

Description

Emergence

Timepoint

During induction of anesthesia until the removal of the laryngeal mask airway after surgery

Method of measurement

The laryngeal mask removal and when the baby opens his/her eyes and moves the four limbs purposefully.

2

Description

Systolic blood pressure

Timepoint

At the time of initiation of the induction, onset of surgery, injection of the drug, 5 minutes after the injection, removal of the laryngeal mask, arrival to the recovery, 30 minutes after the injection, recovery discharge

Method of measurement

Monitoring

3

Description

Diastolic blood pressure

Timepoint
At the time of initiation of the induction, onset of surgery, injection of the drug, 5 minutes after the injection, removal of the laryngeal mask, arrival to the recovery, 30 minutes after the injection, recovery discharge

Method of measurement
Monitoring

Secondary outcomes

1

Description
Dysrhythmia

Timepoint
The onset of anesthesia induction, the onset of surgery, the injection time of caffeine citrate or placebo, removal of the laryngeal mask ,When the child leaves the operating room to enter the recovery room.

Method of measurement
Monitoring

2

Description
Nausea and Vomiting

Timepoint
The onset of anesthesia induction, the onset of surgery, the injection time of caffeine citrate or placebo, removal of the laryngeal mask ,When the child leaves the operating room to enter the recovery room.

Method of measurement
Observation

3

Description
Cyanosis

Timepoint
The onset of anesthesia induction, the onset of surgery, the injection time of caffeine citrate or placebo, removal of the laryngeal mask ,When the child leaves the operating room to enter the recovery room.

Method of measurement
Observation

Intervention groups

1

Description
Intervention group: sevfluorine is discontinued in the suturing process and 20 cc syringes containing 10 mg / kg of caffeine citrate diluted with distilled water will be administered to the patients in the intervention group.ge

Category
Treatment - Drugs

2

Description

Control group: : In the control group,patients received 20 cc of distilled water in 20cc syrin

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Sudabeh Emami
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
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Position
Physician/pediatric anesthesia fellowship
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our policies.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable