Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Respiratory adverse events in children with mild upper respiratory infection: intravenous corticosteroid compared to placebo, randomized blinded clinical trial

Protocol summary

Summary

Patients: Two hundered pediatric patients (1-6 Y), candidate for ophthalmology examination under anesthesia (which cannot be postponed for 6 weeks) with mild upper respiratory tract infection (URI) (based on Parnis criteria) are enrolled. Intervention: After taking written informed consent from parents or gaurdians, they are randomized to blindly receive intravenous corticosteroid (group c) or placebo (group P), ten minutes before anesthesia. Same protocol of anesthesia with sevoflurane and LMA were conducted for both groups. Inclusion criteria would be as follow:1- recent (started within two week) upper respiratory infection (URI).2- Mild URI (based on Parnis criteria). 3- anesthesia could not be postponed for 6 weeks later. 4- ASA class II and exclusion criteria as follow: 1- Difficult airway. 2- Cardiac condition. 3- Drug allergy. 4- Change in surgery or anesthesia plan (more drug prescriptions other than protocol) 5- long lasting surgery (more than an hour) Measurement: Perioperative outcomes (cough. desaturation, laryngospasm, bronchospasm vomiting and re-admission to hospital for respiratory problems) were assessed in recovery and 7 days later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307023436N2**
Registration date: **2013-07-18, 1392/04/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-07-18, 1392/04/27

Registrant information

Name

Babak Gharaei

Name of organization / entity

Labbafijejad Hospital, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2254 9029

Email address

b.gharaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Anesthesiology Department of Labbafinejad Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2013-08-03, 1392/05/12

Expected recruitment end date

2014-02-03, 1392/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Respiratory adverse events in children with mild upper respiratory infection: intravenous corticosteroid compared to placebo, randomized blinded clinical trial

Public title

Is corton beneficial for pediatric patients with coryza undergoing anesthesia?

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion:1- recent (started within two week) upper respiratory infection (URI).2- Mild URI (based on Parnis criteria). 3- anesthesia could not be postponed for 6 weeks later. 4- ASA class II Exclusion: 1- Difficult airway. 2- Cardiac condition. 3- Drug allergy. 4- Change in surgery or anesthesia plan (more drug prescriptions other than protocol) 5- long lasting surgery (more than an hour)

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak St

City

Tehran

Postal code

Approval date

2012-12-10, 1391/09/20

Ethics committee reference number

400/8641

Health conditions studied

1

Description of health condition studied

Acute Nasopharyngitis

ICD-10 code

J00

ICD-10 code description

Coryza (acute)Nasal catarrh, acuteNasopharyngitis

Primary outcomes

1

Description

Cough

Timepoint

(after intervention) Recovery, and 7 days later

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Desaturation (SPO2 less than 92%)

Timepoint

(after intervention) Induction, Maintenance, Emergence and Recovery

Method of measurement

Continious pulse oximetry

2

Description

Partial Laryngospasm (inspiratory stidor)

Timepoint

(after intervention) Induction, maintenance, Emergence and Recovery

Method of measurement

Continious observation

3

Description

Bronchospasm (expiratory wheeze)

Timepoint

(after intervention) Induction, maintenance, emergence and recovery

Method of measurement

Lung auscultation

4

Description

Vomiting

Timepoint

(after intervention) Induction, maintenance, emergence and recovery

Method of measurement

Observation

5

Description

Re-admission within a week after discharge (respiratory related)

Timepoint

(after intervention) 7 days after anesthesia

Method of measurement

Telephone asking

Intervention groups

1

Description

Intervention: Intravenous Hydrocortisone (1mg/kg) and dexamethasone slow iv injection (0.1 mg/kg) , ten minutes before anesthesia

Category

Prevention

2

Description

Control: Intravenous normal sailine with same volume injected in the intervention group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

Full name of responsible person

Babak Gharaei

Street address

Anesthesiology Department, Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Anesthesiology,Labbafinejad Hospital, Shahid Beheshti University of Medical Sciences,

Full name of responsible person

Homayoun Aghamohammadi

Street address

Department of Anesthesiology,Labbafinejad Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Department of Anesthesiology,Labbafinejad Hospital, Shahid Beheshti University of Medical Sciences,

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Anesthesiology Research Center, Labbafinejad Hospital, Shahid Beheshti University of Medical Science

Full name of responsible person

Babak Gharaei

Position

Assistant professor

Other areas of specialty/work

Street address

Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

City

Tehran

Postal code

00982123602175

Phone

+98 21 2360 2175

Fax

Email

babakgharaei@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Anesthesiology Research Center, Labbafinejad hospital, Shahid Beheshti University of Medical Science

Full name of responsible person

Babak Gharaei

Position

Assistant professor

Other areas of specialty/work

Street address

Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

City

Tehran

Postal code

00982123602175

Phone

+98 21 2360 2175

Fax

Email
babakgharaei@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Anesthesiology Research Center, Labbafinejad hospital, Shahid Beheshti University of Medical Science
Full name of responsible person
Babak Gharaei
Position
Assistant professor
Other areas of specialty/work
Street address
Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2360 2175
Fax
+98 21 2254 9029
Email
babakgharaei@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty