

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the hemodynamic effects of nebulized Dexmedetomidine and nebulized Lidocaine in children undergoing fiberoptic bronchoscopy

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparing the hemodynamic effects of nebulized Dexmedetomidine and nebulized Lidocaine in children undergoing fiberoptic bronchoscopy

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Design

This is a double-blind randomized clinical trial with parallel groups. The sample size is 25 people in each group. Randomization using random numbers table.

Registrant information

Name

Amir Shafa

Name of organization / entity

Isfahan University of Medical Sciences, Imam hossein Hospital

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 2655

Email address

amir_shafa@med.mui.ac.ir

Settings and conduct

This study will be conducted at Imam Hossein Children's Hospital in Isfahan. Patient, lung specialist and evaluator are blinded to patient group allocation

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

The inclusion criteria will be 1 to 6 years old, being a candidate for fiberoptic bronchoscopy of ASA1 and ASA2 classes, and having consent for participation. The non-entry criteria will be having any diagnosed cardiac or liver diseases, having a fever, existence of crackle or bronchi when hearing the lungs, intubation, and using other anesthetics or sedative drugs before the bronchoscopy

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group 1: will receive premedication with 2 µg/kg of nebulized Dexmedetomidine, Intervention group 2: will receive premedication with nebulized Lidocaine 1% (4 mg/kg) and control group will receive premedication with saline 0.9%

Scientific title

Comparing the hemodynamic effects of nebulized Dexmedetomidine and nebulized Lidocaine in children undergoing fiberoptic bronchoscopy

Main outcome variables

Hemodynamic changes (Systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, and heart rate)

Public title

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026866N9**

Registration date: **2018-10-06, 1397/07/14**

Nebulized Dexmedetomidine and Nebulized Lidocaine in children undergoing fiberoptic bronchoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 1 and 6 years, Candid for fibropetic bronchoscopy, ASAI,ASAI, Satisfaction to enter the study

Exclusion criteria:

The non-entry criteria are having any diagnosed cardiac or liver diseases, having a fever, existence of crackle or ronchi when hearing the lungs, intubation, and using other anesthetics or sedative drugs before the bronchoscopy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient, lung specialist and evaluator are blinded to patient group allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjrib Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Approval date

2016-08-01, 1395/05/11

Ethics committee reference number

ir.mui.rec.1395.3.505

Health conditions studied

1

Description of health condition studied

Broncoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemodynamic effects

Timepoint

5,10,15,20 minutes after bronchoscopy

Method of measurement

Anesthetic monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:will receive premedication with 2 µg/kg of nebulized Dexmedetomidine by recovery nurse

Category

Treatment - Drugs

2

Description

Intervention group 2: will receive premedication with nebulized Lidocaine 1% (4 mg/kg) by recovery nurse

Category

Treatment - Drugs

3

Description

Control group: will receive premedication with saline 0.9% by recovery nurse

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamhossein hospital

Full name of responsible person

Amir Shafa

Street address

Emamhossein hospital, Emamkhomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

shafa_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezarjrib Ave, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Amir Shafa

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Emamhossein hospital, Emamkhomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Fax**Email**

shafa_amir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amir Shafa

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Emamhossein hospital, Emamkhomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

shafa_amir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amir Shafa

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Emamhossein hospital, Emamkhomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Phone

+98 31 3773 5509

Email

shafa_amir@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Access is available to all researchers

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Amir shafa: shafa_amir@yahoo.com

What processes are involved for a request to access data/document

Request via email

Comments