

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

A comparative study on the effects of open and closed endotracheal suction systems on arterial blood gas parameters of children in pediatric intensive care unit

Protocol summary

Study aim

compare the effects of open and closed endotracheal suction systems on arterial blood gas (ABG) parameters of children admitted to ICUs

Design

This double-blind randomized clinical trial will compare the effects of the open suction system and closed suction system on ABG parameters in children admitted to the PICU

Settings and conduct

The study is done at Imam Hossein Hospital in Isfahan. The way of blindness is that the patient and the researcher do not know the groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: stable hemodynamic conditions (blood pressure 72-102/104-120 mmHg, heart rate 75-100 bpm), ejection fraction (EF) > 50%, sufficient tissue perfusion (capillary refill < 2 s and normal urine output, i.e. 1.0 cc/kg), a body temperature of 35.5-38.5 °C, normal hematocrit (36%-50%), normal hemoglobin (12-17 g/dl), normal PaO₂ (80-100 mmHg), normal SO₂ (95%-100%), normal PaCO₂ (35-45 mmHg), normal HCO₃ (22-28 mmHg), and normal pH (7.35- 7.45). Patients with obstructive pulmonary disease were not recruited. The participants were excluded if they were extubated or discharged against medical advice (with parental consent), or if they died before the end of the study.

Intervention groups

The selected children were randomly (alternately) allocated to two equal groups to receive either open or closed suction.

Main outcome variables

Arterial Blood Gas status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026866N6**

Registration date: **2018-07-04, 1397/04/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-04, 1397/04/13**

Update count: **0**

Registration date

2018-07-04, 1397/04/13

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

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-25, 1397/04/04

Expected recruitment end date

2018-09-25, 1397/07/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effects of open and closed endotracheal suction systems on arterial blood gas parameters of children in pediatric intensive care unit

Public title

A comparative study on the effects of open and closed endotracheal suction systems on arterial blood gas parameters of children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

stable hemodynamic conditions (blood pressure 72-102/104-120 mmHg, heart rate 75-100 bpm), ejection fraction (EF) > 50%, sufficient tissue perfusion (capillary refill < 2 s and normal urine output, i.e. 1.0 cc/kg), a body temperature of 35.5-38.5 °C, normal hematocrit (36%-50%), normal hemoglobin (12-17 g/dl), normal PaO₂ (80-100 mmHg), normal SO₂ (95%-100%), normal PaCO₂ (35-45 mmHg), normal HCO₃ (22-28 mmHg), and normal pH (7.35- 7.45).

Exclusion criteria:

Lack of obstructive pulmonary disease

Age

From **3 months** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

patients and the researcher don not know the type of suction apply

Placebo

Not 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

Imam Hossein Hospital, Imam khomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8185665843

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

ir.mui.rec.1396.3.95401

Health conditions studied

1

Description of health condition studied

This study aime to compare the effects of open and closed endotracheal suction systems on arterial blood gas (ABG) parameters of children admitted to ICUs

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Arterial blood gas status

Timepoint

1,5,15 minute after suction

Method of measurement

Arterial blood gas measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Suction is done with a closed system

Category

Treatment - Devices

2

Description

Control group: Suction is done with open system

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Amir Shafa

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Imam Hossein Hospital, Imam khomeini Ave

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Isfahan

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8185665843

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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

Hezerjrib Ave.

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8185665735

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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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

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

Title and more details about the data/document

All data

When the data will become available and for how long

6 Month after print results

To whom data/document is available

All people

Under which criteria data/document could be used

No special condition

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