

# 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 PaO<sub>2</sub> (80-100 mmHg), normal SO<sub>2</sub> (95%-100%), normal PaCO<sub>2</sub> (35-45 mmHg), normal HCO<sub>3</sub> (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 PaO<sub>2</sub> (80-100 mmHg), normal SO<sub>2</sub> (95%-100%), normal PaCO<sub>2</sub> (35-45 mmHg), normal HCO<sub>3</sub> (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

**Street address**

Imam Hossein Hospital, Imam khomeini 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**

Hezerjrib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

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

**Street address**

Imam hossein Hospital, Imam Khomeini Ave

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## 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

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Specialist

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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**