Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Oct 2026

Accuracy of pulse oximetry in detection of oxygen saturation in patients admitted to the intensive care unit of heart surgery: comparison of finger, toe, forehead and earlobe probes

Protocol summary

Study aim

Comparison of the Oxyhemoglobin saturation accuracy in pulse oximeters of the fingers, toes, foreheads, and ears in patients undergoing open heart surgery

Design

Trial without control group, before and after, without blindness

Settings and conduct

The present study will be conducted in the intensive care unit. At first, 2 cc of blood is taken from each of the samples through the arterial catheter. The blood samples in a container of ice will be sent immediately to the laboratory. In the form of arterial blood gas analysis, hemoglobin and body temperature are also recorded. Tympanic thermometer is used to determine the patient's temperature. All patients will be in the supine position while the head of the bed is 30 degrees above the body level. To prevent ambient light from interfering with the operation of each of the four types of pulsed oximetry probes, a cover is placed around the probes. The amount of spo2 from four types of the forehead, ear, toe and finger probes will be measured simultaneously by sampling arterial blood gas at a time interval of 0, 1, 2, 3, 4, and 5 minutes. All probes are calibrated before use. The average difference between the amount of sao2 and spo2 and the agreement between them will be calculated using the Bland-Altman analysis. The higher the agreement, the more accurate the probe is.

Participants/Inclusion and exclusion criteria

Open heart surgery patients, lack of left ventricular failure, lack of peripheral vascular disease, lack of renal failure, and temperatures above 35 °C

Intervention groups

The intervention involves the placement of four types of pulsed oximetry probes in the forehead, ear, fingers and toes.

Main outcome variables

arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100913004736N22**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **retrospective**

Last update: **2018-03-19, 1396/12/28**
Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 3827 9394

Email address

akhatony@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-30, 1397/01/10

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2017-04-09, 1396/01/20

Trial completion date

empty

Scientific title

Accuracy of pulse oximetry in detection of oxygen saturation in patients admitted to the intensive care unit of heart surgery: comparison of finger, toe, forehead and earlobe probes

Public title

Comparison of pulse oximeter accuracy in determining oxygen saturation

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Have been undergoing open heart surgery Have an arterial line Temperature higher than 35 ° C Hemoglobin greater than 9 g/dl Mean arterial blood pressure above 60 mm Hg PaO2 between 70 to 100% PCo2 less than 45 mm Lack of hematologic problems (anemia, methemoglobinemia, carboxyhemoglobinemia) The absence of left ventricular dysfunction, peripheral vascular disease, acute and chronic renal failure The absence of clubbing fingers No history of smoking The absence of scars, burns, edema, and dressing in place of probing Not receiving medications that affect blood vessel diameter

Exclusion criteria:

Patients requiring suction Patients need to change position

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **67**

Actual sample size reached: **67**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshty Blvd., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

62663455667

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

ir.kums.rec.1396.710

Health conditions studied

1

Description of health condition studied

cardiovascular diseases

ICD-10 code

R94.30

ICD-10 code description

Abnormal result of cardiovascular function study, unspecified

Primary outcomes

1

Description

Percentage of arterial oxygen saturation

Timepoint

At intervals of zero, one, two, three, four, and five minutes

Method of measurement

Using five pulse oximetry probes

Secondary outcomes

1

Description

Arterial oxygen concentration(Pao2)

Timepoint

Once at the beginning of the intervention

Method of measurement

By taking arterial blood sample

Intervention groups

1

Description

The intervention group is the patients undergoing cardiac surgery. At the beginning of the study, the

oxygen levels of the arterial blood of all samples will be measured.Then the pulse oximeter probes will be placed in the forehead, ear, throat, fingers, toes, and nose. At intervals of zero, one, two, three, four, and five minutes, the amount of arterial oxygen saturation will be measured by pulse oximeter.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Alireza Khatony

Street address

Imam Ali Hospital, Shahid Beheshty Blvd., Kermanshah, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

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Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah, Iran

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Khatony

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

The main consequence is the possibility of sharing information.

When the data will become available and for how long

Six months after the publication of the article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is no right to extract the article from the documentation.

From where data/document is obtainable

Dr. Alireza Khatony

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

Within a week of receiving the email, it will be answered.

Comments