

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of prone and supine positions on arterial blood oxygen saturation and vital signs of premature newborn

Protocol summary

Summary

This is a cross sectional clinical trial in which premature newborns with the gestational age between 32 to 36 weeks and birth age of 2 days to 4 weeks admitted to Neonatal Intensive Care Unit will be placed in the two groups with paired block. In the first stage, after selecting the samples, the intervention and control groups will be selected and in the second stage the two groups will be switched. To do the work, at first each newborn will be positioned laterally for 15 minutes and then placed in prone or supine position for 3 hours. After 3 hours, the newborn will be positioned laterally for 15 minutes again and then placed in the opposite position for 3 hours. For each newborn arterial blood oxygen concentration, heart rate, respiratory rate and body temperature will be documented every 15 minutes for 3 hours. The main goal is determining the effect of two prone and supine positions on premature newborns' blood oxygen concentration and vital signs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041633471N1**

Registration date: **2017-09-27, 1396/07/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Hamid Torabian

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3293 6248

Email address

h.torabian@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-09-16, 1396/06/25

Expected recruitment end date

2017-10-17, 1396/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of prone and supine positions on arterial blood oxygen saturation and vital signs of premature newborn

Public title

Comparing the effect of prone and supine positions on arterial blood oxygen saturation and vital signs of premature newborn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age between 32-36 weeks; birth age of 2 days to 4 weeks; weight at least 1000 grams; not using ventilator; spontaneous breathing; maximum oxygen concentration of 5 liter/minute if using oxygen by hood or incubator; free of congenital anomalies, free of active bleeding; not having blood

problems; methemoglobinemia;
carboxyhemoglobinemia; hemoglobin greater than 9
gr/dl; not using narcotics, corticosteroids, and surfactant
Exclusion criteria: connecting to ventilator; infecting with
pneumothorax; death; parental dissatisfaction with
continuing the work; need to perform CPR

Age

From **2 days** old to **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

In this study, after selecting the samples based on inclusion criteria, the samples will be placed in the two intervention and control groups with paired block randomization. In addition to arterial blood oxygen concentration, at the same time premature newborns' vital signs such as respiratory rate, heart rate and body temperature will be monitored and documented.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical
Sciences

Street address

Deputy of research and technology;Third Floor;Imam
Musa Kazim Building;Academic Complex of the
Payamber ; Basij Square;Arak;Markazi Province

City

Arak

Postal code

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.ARAKMU.REC.1395.448

Health conditions studied

1

Description of health condition studied

Sleep state to the abdomen and back

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Arterial Blood Oxygen Saturation

Timepoint

Every 15 minutes to 3 Hours

Method of measurement

Puls Oximeter

2

Description

Heart Rate

Timepoint

Every 15 minutes to 3 hours

Method of measurement

Puls Oximeter

3

Description

Breath Rate

Timepoint

Every 15 minutes to 3 hours

Method of measurement

Chest lead

4

Description

Temperature

Timepoint

Every 15 minutes to 3 hours

Method of measurement

SkinThermometer

Secondary outcomes

empty

Intervention groups

1

Description

Second Intervention:sleep newborn on supine position for
3 hours

Category

Other

2

Description

First intervention: Sleep newborn on prone position for 3

hours
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Hamid Torabian

Street address

Amir Kabir Hospital, Parastar Sq, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of
Medical Sciences

Full name of responsible person

Ali Arash Anoshiravani

Street address

Deputy of research and technology, Third Floor, Imam
Musa Kazim Building, Academic Complex of the
Payambar , Basij Square, Arak; Markazi Province

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Arak 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

Vice chancellor for research, Arak University of
Medical Sciences

Full name of responsible person

Ali Arash Anoshiravani

Position

Blood specialist and oncology

Other areas of specialty/work

Street address

Deputy of research and technology, Third Floor, Imam
Musa Kazim Building, Academic Complex of the
Payambar , Basij Square, Arak; Markazi Province

City

Arak

Postal code

Phone

+98 86 3417 3638

Fax

+98 86 3417 3639

Email

Research@arakmu.ac.ir

Web page address

www.arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Arak University of
Medical Sciences

Full name of responsible person

Doc Sharareh khosravi

Position

phD nursing

Other areas of specialty/work

Street address

Blue Bal, School of Nursing and Midwifery , Academic
Complex of Prophet Muhammad (PBUH, Sardasht,
Basij Sq, Arak

City

Arak

Postal code

Phone

+98 86 3417 3503

Fax

Email

shararehkh2011@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Arak University of
Medical Sciences

Full name of responsible person

Hamid Torabian

Position

MSN

Other areas of specialty/work

Street address

City

Postal code

Phone

+98 25 3291 1958

Fax

Email

h.torabian@arakmu.ac.ir

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