

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Determination of mother oxygen therapy on neonate's umbilical vein blood Gas after cesarean section under spinal anaesthesia.

Protocol summary

Summary

This study will be conducted as randomized clinical trial with control group to evaluate the effect of mother oxygen therapy on neonatal umbilical venous blood gas. Target population consists of one hundred healthy full term pregnant women that was candidate for cesarean section surgery. The inclusion criteria are: Single pregnancy, Body mass index less than 35 and class1 American Society of Anesthesiologists physical status classification system. Exclusion criteria will be: having underlying disease, fetal distress, having multiple pregnancies, non cephalic presentation and using ephedrine during surgery, fetal anomaly and after birth. Women will be assigned to two groups consist of 50 persons in each. In first group after regional anaesthesia, 40 % oxygen by facial mask will be administered and the second group will be let breath in the room air condition. Before and after oxygen therapy o2 saturation of mothers will be measured, after birth the umbilical cord will be clamped and venous blood cord will be sent for laboratory analysis. The apgar score will be documented and results will be statistically compared between study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103011107N5**

Registration date: **2011-04-26, 1390/02/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-26, 1390/02/06

Registrant information

Name

Tajea Jadery

Name of organization / entity

Jundi shapur university

Country

Iran (Islamic Republic of)

Phone

-

Email address

research@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapour Medical University

Expected recruitment start date

2010-06-28, 1389/04/07

Expected recruitment end date

2011-02-02, 1389/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of mother oxygen therapy on neonate's umbilical vein blood Gas after cesarean section under spinal anaesthesia.

Public title

Determination of mother oxygen therapy on neonate's umbilical vein blood Gas after cesarean section under spinal anaesthesia.

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria : elective cesarean, full term pregnancies, BMI<35, ASA class I, single pregnancy.
exclusion criteria : Maternal hypotension, fetal distress,

fetal anomaly after birth, need for ephedrin administration.

Age
From **17 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz Jondishapur University of Medical Sciences

Street address

Golestan bolvar,Ahwaz

City

Ahvaz

Postal code

Approval date

2010-06-07, 1389/03/17

Ethics committee reference number

ETh087

Health conditions studied

1

Description of health condition studied

Anaesthetics and therapeutic gases

ICD-10 code

Y48.5

ICD-10 code description

Therapeutic gases

Primary outcomes

1

Description

O2 sat Of umbilical vein

Timepoint

immediately after birth and only one time

Method of measurement

by using ABG analyser

Secondary outcomes

1

Description

po2

Timepoint

immediately after birth and only one time

Method of measurement

by ABG analyser

Intervention groups

1

Description

case group: oxygen 4 liters per minute -duration: since starting of anesthesia untill termination of surgery-
method: by facial mask

Category

Treatment - Other

2

Description

control group: no intervention was done-using air room

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Dr Afshin Mokfi, Resedent Of Anaesthesia

Street address

Emam Hospital, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapour University of Medical Science

Full name of responsible person

Dr Mostafa Fegghi, Vice-Chancellor For Research

Street address

Vice-Chancellor For Research, Ahvaz Jundishapour
University of Medical Science

City
Ahvaz

Grant name

Grant code / Reference number
-

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

Title of funding source
Ahvaz Jundishapour University of Medical Science

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
Ahvaz Jundishapour Medical University

Full name of responsible person
Dr Reza Akhoundzade

Position
Assistant professor of Anaesthesia

Other areas of specialty/work

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Person responsible for updating data

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Jundishapour University Of medical sciences

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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