Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 peregnancies, 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 umblical vein

Timepoint
immediately after birth and only one time

Method of measurement
by useing 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 Feghhi, Vice-Chancellor For Research
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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
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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