Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Maternal and Neonatal Effects of two different dosages of Remifentanil at Induction of General Anesthesia for Cesarean Delivery

Protocol summary

Summary

This study is aimed to evaluate the effects of two different dosages of remifentanil infusion on Apgar score of neonates and awareness of mothers during general anesthesia for elective cesarean section. This double-blind clinical trial was performed on 90 participants aged between 18 and 35 years undergoing elective cesarean section who are randomly assigned into three equal groups. The patients will receive infusion of remifentanil 0.2µg/kg/min, remifentanil 0.1µg/kg/min, or normal saline with the same volume and rate in the control group. Before infusion and just before and after tracheal intubation and 5 min after that, systolic and diastolic blood pressure and heart rates of the mothers were recorded. Apgar scores of neonates were recorded at first and 5th minutes after birth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105162883N2**
Registration date: **2011-05-26, 1390/03/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-26, 1390/03/05

Registrant information

Name

Mohammadreza Habibi

Name of organization / entity

Mazandarn University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Mazandaran University of Medical Sciences and Health Services

Expected recruitment start date

2009-12-30, 1388/10/09

Expected recruitment end date

2010-06-21, 1389/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Maternal and Neonatal Effects of two different dosages of Remifentanil at Induction of General Anesthesia for Cesarean Delivery

Public title

Effects of two different dosages of Remifentanil at Induction of General Anesthesia for Cesarean Delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women aged 18-35 years with American Society of Anesthesiologist physical status class I- II, candidate for elective cesarean section under general anesthesia Exclusion criteria: associated disease such as preeclampsia, hypertension, history of difficult intubation, cardiovascular or respiratory disorders, diabetes

Age

From **18 years** old to **35 years** old

Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for Research of Mazandaran University of Medical Sciences and Health Services
Street address
Moalem Street, Moalem Square
City
Sari
Postal code
Approval date
2009-12-30, 1388/10/09
Ethics committee reference number
88-117

Health conditions studied

1

Description of health condition studied
Complications of anaesthesia during labour and delivery
ICD-10 code
O74.2
ICD-10 code description
Complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
Blood pressure of the mothers
Timepoint
Before infusion and just before and after tracheal intubation and 5 min after that-
Method of measurement
BP Monitoring

2

Description
Heart rates of the mothers.
Timepoint
Before infusion and just before and after tracheal intubation and 5 min after that
Method of measurement
ECG Monitor and pulseoxymetry

3

Description
Apgar score of neonates
Timepoint
At the first and 5th minutes after birth
Method of measurement
by the pediatrician coinvestigator

Secondary outcomes

empty

Intervention groups

1

Description
Control group: normal saline will be infused by the same volume and rate
Category
Placebo

2

Description
Intervention group A: infusion of remifentanil 0.2µg/kg/min
Category
Treatment - Drugs

3

Description
Intervention group B: infusion of remifentanil 0.1µg/kg/min
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital, Amir Mazandarani boulevard
Full name of responsible person
Mohammadreza Habibi MD.
Street address

City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice Chancellor of Mazandaran University of Medical Sciences and Health Services
Full name of responsible person
Dr. Ahmadali Enayati
Street address
Moalem street- Moalem square
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice Chancellor of Mazandaran University of Medical Sciences and Health Services
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
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Person responsible for updating data

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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