

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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 remifentanyl
0.2µg/kg/min

Category

Treatment - Drugs

3**Description**

Intervention group B: infusion of remifentanyl
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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Habibi

Position

Associate Professor of Anesthesiology, member of
faculty,

Other areas of specialty/work

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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