

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Maternal and neonatal effects of remifentanil in general anaesthesia for Caesarean delivery

Protocol summary

Summary

The purpose of this study was to evaluate the effects of remifentanil on hemodynamic variables in mothers, APGAR, and umbilical artery PH in neonates in the women undergoing general anesthesia for semi-elective cesarean section in Shahid Sadoughi hospital in YAZD, IRAN. In a randomized double blind trial, 80 women with term pregnancy, aged 18-35 years old, and ASA physical status I, were studied in two groups. Patients in intervention group (n=40) received an intravenous bolus of 0.5 µg/kg remifentanil whereas, women in control group (n=40) received the same dose of saline as placebo, immediately before induction of anesthesia. Maternal hemodynamic variables (systolic, diastolic, mean blood pressure, and heart rate) as well as neonatal umbilical artery PH and Apgar score at 1 and 5 min were evaluated in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102252963N2**
Registration date: **2011-04-16, 1390/01/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-16, 1390/01/27

Registrant information

Name

Shekoufeh Behdad

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 1386

Email address

drbehdad@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2010-04-19, 1389/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Maternal and neonatal effects of remifentanil in general anaesthesia for Caesarean delivery

Public title

Maternal and neonatal effects of remifentanil in general anaesthesia for Caesarean delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with American Society of Anesthesia (ASA) physical status I or II and singleton term pregnancies who are candidate for cesarean section that is not emergent
Exclusion criteria: Anaphylaxis reaction to the anesthetic drugs, excessive bleeding during the operation

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

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

Shahid Sadoughi University of Medical Sciences

Street address

Bahonar square

City

Yazd

Postal code

Approval date

2009-02-11, 1387/11/23

Ethics committee reference number

107532

Health conditions studied

1

Description of health condition studied

Remifentanil

ICD-10 code

Y45.0

ICD-10 code description

Opioids and related analgesics

Primary outcomes

1

Description

diastolic blood pressure

Timepoint

before of induction of general anesthesia,immediately after laryngoscopy and intubation, after incision of skin, after delivery of fetus

Method of measurement

NIBP monitoring

2

Description

systolic blood pressures

Timepoint

before of induction of general anesthesia,immediately after laryngoscopy and intubation, after incision of skin, after delivery of fetus

Method of measurement

NIBP monitoring

3

Description

mean arterial pressure

Timepoint

before of induction of general anesthesia,immediately after laryngoscopy and intubation, after incision of skin, after delivery of fetus

Method of measurement

NIBP monitoring

4

Description

heart rate in mother

Timepoint

before of induction of general anesthesia,immediately after laryngoscopy and intubation, after incision of skin, after delivery of fetus

Method of measurement

EKG monitoring

Secondary outcomes

1

Description

APGAR score in the neonate

Timepoint

1 and 5 minutes after birth

Method of measurement

APGAR score

2

Description

umbilical cord PH

Timepoint

After delivery

Method of measurement

blood gas analysis

Intervention groups

1

Description

An intravenous bolus of 0.5 µg/kg remifentanil immediately before induction of anesthesia

Category

Treatment - Drugs

2

Description

The same volume of saline as remifentanyl, intravenously, as placebo, immediately before induction of anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr. Shekoufeh Behdad

Street address

Shahid Sadoughi Hospital, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Hasan Mozaffari

Street address

Bahonar square

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi 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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Shekoufeh Behdad

Position

Manager of anesthesia group

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital

City

Yazd

Postal code

Phone

+98 35 1822 4104

Fax

Email

drbehdad@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Shekoufeh Behdad

Position

Anesthesiologist

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital

City

Yazd

Postal code

Phone

+98 35 1822 4104

Fax

Email

drbehdad@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Shekoufeh Behdad

Position

Manager of Anesthesia group

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital

City

Yazd

Postal code

Phone

+98 35 1822 4104

Fax

Email

drbehdad@yahoo.com

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