

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of effects of Remifentanil and Fentanyl in blood pressure and heart rate changes due to tracheal intubation in preeclamptic pregnant women candidate for cesarean section

Protocol summary

Summary

This study was a single blinded randomised clinical trial to compare blood pressure and heart rate changes due to tracheal intubation in preeclamptic pregnant women candidate for cesarean section under general anesthesia. total sample size was 34 (17 in two groups). Inclusion criteria: cesarean section in preeclamptic women in 20-40 y. without any history of cardiac, pulmonary or hepatic disorders before pregnancy and no allergic drug reactions or addiction. Patients were randomly divided in two groups. after receiving adequate loading fluid, in group1 0.05 microgram/kg Remifentanil infused for 3 minutes before induction of anesthesia and in group2, 50 microgram(1 milliliter) Fentanyl injected and anesthesia induced after 3 minutes with Thiopental and Succinyl cholin. Heart rate, systolic and diastolic blood pressure were measured automatically before opioid injection, before and after tracheal intubation. , Newborn Apgar Score was measured at birth and 5th minute after birth as a secondary outcome to evaluate the possible effects of drugs on newborn condition.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108294969N2**
Registration date: **2011-09-22, 1390/06/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-22, 1390/06/31

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

drpournajafian@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2007-03-21, 1386/01/01

Expected recruitment end date

2009-03-21, 1388/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of Remifentanil and Fentanyl in blood pressure and heart rate changes due to tracheal intubation in preeclamptic pregnant women candidate for cesarean section

Public title

Comparison of effects of Remifentanil and Fentanyl in blood pressure and heart rate changes due to tracheal intubation in preeclamptic pregnant women candidate for cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: pregnant women with preeclampsia, between 20 and 40 years old, candidate for elective or emergency cesarean section

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Next to Milad Tower, Hemmat Highway

City

Tehran

Postal code

Approval date

2007-02-04, 1385/11/15

Ethics committee reference number

4276

Health conditions studied

1

Description of health condition studied

preeclampsia

ICD-10 code

O14

ICD-10 code description

Gestational [pregnancy-induced] hypertension with significant proteinuria

Primary outcomes

1

Description

systolic blood pressure

Timepoint

before induction of anesthesia, before tracheal intubation, after tracheal intubation

Method of measurement

automatic

2

Description

diastolic blood pressure

Timepoint

before induction of anesthesia, before tracheal intubation, after tracheal intubation

Method of measurement

automatic

3

Description

heart rate

Timepoint

before induction of anesthesia, before tracheal intubation, after tracheal intubation

Method of measurement

puls oxymeter

Secondary outcomes

1

Description

apgar score of newborn

Timepoint

1st and 5th minute after birth

Method of measurement

number 1 to 10 , depending on breathing, heart rate, skin color,

Intervention groups

1

Description

injection of 0.05 microgram/kg Remifentanyl during 3 minutes before induction of anesthesia

Category

Prevention

2

Description

injection of 1 mg/kg Fentanyl 3 minutes before induction of anesthesia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Alireza Pournajafian

Street address

Beh afarin st., Karim khan Ave., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

mrs. jafarpour

Street address

Next to Blood Bank, Hemmat Highway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Science

Full name of responsible person

Alireza Pournajafian

Position

Assistant professor of anesthesia

Other areas of specialty/work**Street address**

Firoozgar Hospital, Beh Afarin st., karim khan Ave.

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax

+98 21 8894 2622

Email

a-pournajafian@tums.ac.ir alipn78@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Science

Full name of responsible person

Alireza Pournajafian

Position

Assistant professor of anesthesia

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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