

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Alfentanil on Hemodynamic Changes due to Endotracheal Intubation in Elective Cesarean Section under General Anesthesia

Protocol summary

Summary

Effects of Alfentanil on Hemodynamic Changes due to Endotracheal Intubation in Elective Cesarean Section under General Anesthesia. methods: randomized clinical trial, double blinded. control group with placebo, one central. A: population of study patient aged 20_40 years. inclusion criteria: patient age 20_40 year; ASA 1; elective cesarean section. exclusion criteria: emergency cesarean; using antihypertensive drug; analgesic drug and psychiatric drugs. target sample size 50, in this study patient divided randomly in two group A and B, patient in A group first give 10 mic/kg alfentanil for premedication and patient in second group give normal saline as the same volume and maternal hemodynamic changes (systolic blood pressure, diastolic blood pressure, heart rate) was measured before induction and every 2 minutes until delivery and then every 5 minutes to the end of surgery. also saturation of neonate with pulse oxymetry and Apgar scores were measured 1 and 5 minutes after birth and Bispectral index from the beginning of general anesthesia and maternal awareness at the end of surgery measuring up on the checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012012203N1**

Registration date: **2013-11-09, 1392/08/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-09, 1392/08/18

Registrant information

Name

Niloufar Massoudi

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 26 3250 6961

Email address

nmasoudi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Gazvin University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Alfentanil on Hemodynamic Changes due to Endotracheal Intubation in Elective Cesarean Section under General Anesthesia

Public title

Effects of Alfentanil on Hemodynamic Changes due to Endotracheal Intubation in Elective Cesarean Section under General Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patient age 20_40 year; ASA 1; elective cesarean section. exclusion criteria: emergency cesarean; using antihypertensive drug; analgesic drug; psychiatric

drugs.

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: **50**

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

Ghazvin University Of Medical Science

Street address

Ghazvin University Of Medical Science, Navab Avenue
,Ghazvin

City

Ghazvin

Postal code

3413996134

Approval date

2013-05-22, 1392/03/01

Ethics committee reference number

7410/20/28

2

Ethics committee

Name of ethics committee

Gzvin University Of Medical Science

Street address

Gzvin University Of Medical Science,Navab avenue

City

Gazvin

Postal code

Approval date

2013-05-22, 1392/03/01

Ethics committee reference number

7410/20/28

Health conditions studied

1

Description of health condition studied

Elective cesarean under general anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

heart rate

Timepoint

every 2 minute until delivery then every 5 minute to the
end of surgery

Method of measurement

number of heart rate in one minute

2

Description

measuring systolic and diastolic blood pressure

Timepoint

every 2 minute until delivery then every 5 minute to the
end of surgery

Method of measurement

with cuff of blood pressure measuring

Secondary outcomes

1

Description

Bispectral Index

Timepoint

every 2 minute until delivery and then every 5 minute to
the end of surgery

Method of measurement

level of consciousness

2

Description

Saturation of neonate

Timepoint

after birth of neonate measuring

Method of measurement

level of oxygen in arterial blood measuring with pulse
oxymetry

3

Description

apgar score

Timepoint

1 minute and 5 after birth

Method of measurement

level of consciousness in 1 and 5 min after birth

4

Description

awarness

Timepoint

after awaking in recovery

Method of measurement

time of maternal recall

Intervention groups

1

Description

in interventional group patint give 10 mic/kg alfentanil
befor induction

Category

Treatment - Drugs

2

Description

control group give the same volum of intervention group
normal salin befor induction

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

KosarHospital Ghazvin University Of Medical Science

Full name of responsible person

nilofar masoudi

Street address

kosar hospital,Vlieasr Avenue,Gazvin

City

Ghazvin

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor For Research,Ghzvin University Of
Medical Science

Full name of responsible person

Mahnaz abasi

Street address

Ghazvin University Of Medical science,Navab avenu,
Ghazvin

City

Ghazvin

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

Yes

Title of funding source

Vice Chancellor For Research,Ghzvin 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**Name of organization / entity**

Ghazvin University Of Medical Science

Full name of responsible person

Nilofar Masoudi

Position

resident of anesthesia

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

Ghazvin University Of Medical Science,Navab
Avenue,Ghazvin

City

Ghazvin

Postal code

3413996136

Phone

+98 28 1335 9557

Fax

+98 28 1333 5800

Email

nmasoudi@qums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Gazvin University Of Medical Science

Full name of responsible person

nilofar masoudi

Position

Residet of Anesthesia

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

Ghazvin University Of Medical Science Ghazvin,Navab
avenue,Gazvin

City

Ghazvin

Postal code

3413996136

Phone

+98 28 1335 9557

Fax

+98 982813335800

Email

nmasoudi@qums.ac.ir

Web page address

Person responsible for updating data

Contact

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