

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Pethidine, Fentanyl and Sufentanyl on hemodynamic changes in pregnant women candidate for elective cesarean section

Protocol summary

Summary

The aim of this study: Comparison of Pethidine, Fentanyl and Sufentanyl on hemodynamic changes in pregnant women candidate for elective cesarean section. Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be allocated into A, B and C groups. Randomization will be performed using random block sizes of 3. The study is single center, double blind and phase 3 trial and patients and physician will be blind about the type of injection drug. Inclusion criteria: Pregnant women candidates for cesarean section. Exclusion criteria: Diabetes; hypertension; thyroid disease; cardiopulmonary disease; beta agonist and beta blocker use; opium addiction; preeclampsia; eclampsia. Sample size: 90 patients will participate in the study with 30 patients in each group. Study groups: Interventions: Pethidine 1.5 microgram/kg IV single dose. Preoperatively and every 30 minutes. caspian tamin pharmaceutical company, Fentanyl 1.5 microgram/kg IV single dose. Preoperatively and every 30 minutes. caspian tamin pharmaceutical company, Sufentanyl 1.5 microgram/kg IV single dose. Preoperatively and every 30 minutes. caspian tamin pharmaceutical company. Primary outcome: Heart rate and blood pressure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042333611N1**

Registration date: **2017-09-02, 1396/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-02, 1396/06/11

Registrant information

Name

Mahsa Adib

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Islamic Azad University of Shahrood

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pethidine, Fentanyl and Sufentanyl on hemodynamic changes in pregnant women candidate for elective cesarean section

Public title

The effect of Pethidine, Fentanyl and Sufentanyl on hemodynamic changes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women candidates for cesarean section. Exclusion criteria: Diabetes;

hypertension; thyroid disease; cardiopulmonary disease; beta agonist and beta blocker use; opium addiction; preeclampsia; eclampsia.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Shahrood

Street address

Islamic Azad University of Shahrood, Tehran Blvd, Shahrood

City

Shahrud

Postal code

3613773955

Approval date

2017-01-12, 1395/10/23

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1395.16

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Heart rate

Timepoint

Before and during intervention, every 5 minutes up to an hour

Method of measurement

In terms of beats per minute using Monitor

2

Description

Blood pressure

Timepoint

Before and during intervention, every 5 minutes up to an hour

Method of measurement

In terms mercury milimeter using Monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Pethidine 1.5 microgram/kg IV single dose. Preoperatively and every 30 minutes. The drug is produced by Caspian Tamin pharmaceutical company.

Category

Treatment - Drugs

2

Description

Intervention 2: Fentanyl 1.5 microgram/kg IV single dose. Preoperatively and every 30 minutes. The drug is produced by Caspian Tamin pharmaceutical company

Category

Treatment - Drugs

3

Description

Intervention 3: Sufentanyl 1.5 microgram/kg IV single dose. Preoperatively and every 30 minutes. The drug is produced by Caspian Tamin pharmaceutical company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Alanbia Hospital of Shahrood

Full name of responsible person

Yousef Kolukhi

Street address

Khatam Alanbia Hospital, Tehran Blvd, Shahrood

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Shahrood

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Yousef Kolukhi

Position

Anesthesiologist

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for Research and Technology, Islamic
Azad University of Shahrood**Full name of responsible person**

Sahebali Manafi

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Islamic Azad University of Shahrood, Tehran Blvd

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Shahrood

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

Yes

Title of funding sourceVice chancellor for Research and Technology, Islamic
Azad University of Shahrood**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**

Islamic Azad University of Shahrood

Full name of responsible person

Mahsa Adib

Position

Medical Student

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Full name of responsible person

Yousef Kolukhi

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Anesthesiologist

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Fax**Email****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