

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

Protocol summary

Study aim

determination and comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

Design

Randomised, controlled , parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an excel

Settings and conduct

This study is a randomized double-blind clinical trial that randomization will be done by usind random numbers. this study will be done in Beheshti Hospital.

Participants/Inclusion and exclusion criteria

Age between 18 to 45 years old ASA number 1 and 2 Patient is cesarian candida that term pregnancy Patient has no disease like hypertention Patient has no uncontrolled diabet Patient has no allergy to ondansetron or local anesthtic drug no forbid for spinal anesthesia Patient dosent use drugs which effect on HT35 receptor

Intervention groups

Patients will be randomly divided into three groups consist of receiving 6 mg of ondansetron, 8 mg of ondansetron, and distilled water. They are injected intravenously and then the patients are subjected to spinal anesthesia. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and arterial blood oxygen saturation are measured and recorded every 15 minutes during surgery and every 15 minutes during the recovery period by an observer who is not by the research team. Any complication is recorded if it occurs during appropriate treatment

Main outcome variables

Systolic blood pressure, diastolic blood pressure, heart rate, mean arterial pressure, arterial oxygen saturation, nausea, vomiting, duration of surgery,duration of stay in

recovery,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191109045371N1**

Registration date: **2020-10-14, 1399/07/23**

Registration timing: **retrospective**

Last update: **2020-10-14, 1399/07/23**

Update count: **0**

Registration date

2020-10-14, 1399/07/23

Registrant information

Name

Farhad Hasanvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3625 6966

Email address

farhadhasanvand94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2020-07-21, 1399/04/31

Trial completion date

2020-08-22, 1399/06/01

Scientific title

comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

Public title

comparing the effect of two different doses of ondansetron on heart rate , blood pressure and blood oxygen saturation variation in caesarian surgery under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 45 years old ASA number 1 and 2
Patient is cesarian candida that term pregnancy Patient has no disease like hypertention Patient has no uncontrolled diabet Patient has no allergy to ondansetron or local anesthtic drug no forbid for spinal anesthesia
Patient dosent use drugs which effect on HT35 receptor

Exclusion criteria:**Age**

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study ,patients were divided on a basis of Random block making, into blocks consisting of six peoples.in each block, two patients received 8 milligrams of ondansetron, two patients received 6 milligrams of ondansetron, and two patients received normal saline. then by use of Random digits table, 15 different blocks of the so called blocks were randomly chosen. Drugs were drawn in three syringes of the same size and color by an out-of-study anesthesiologist and for every patient proportionate to his group, were given to the main anesthesiologist. Patient, main anesthesiologist, the person in charge of collecting and recording datas were unaware of the Type of the drug that was used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs were drawn in three syringes of the same size and color by an out-of-study anesthesiologist and for every

patient proportionate to his group, were given to the main anesthesiologist. Patient, main anesthesiologist, the person in charge of collecting and recording datas were unaware of the Type of the drug that was used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

No 48,bijan alley , hakim nezami Ave

City

Isfahan

Province

Isfahan

Postal code

8175976665

Approval date

2019-06-02, 1398/03/12

Ethics committee reference number

IR.MUI.MED.REC.1398.446

Health conditions studied**1****Description of health condition studied**

cesarean section

ICD-10 code

O75.82

ICD-10 code description

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes**1****Description**

Blood pressure

Timepoint

Befor operation and every 15 minute during operation and recovery

Method of measurement

mercury barometer

2

Description

blood oxygen saturation

Timepoint

Befor operation and every 15 minute during operation and recovery

Method of measurement

puls oxymeter

3

Description

heart rate

Timepoint

Befor operation and every 15 minute during operation and recovery

Method of measurement

puls oxymeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: patients take 6 mg ondansetron

Category

Treatment - Drugs

2

Description

Intervention group: patients take 8 mg ondansetron

Category

Treatment - Drugs

3

Description

Control group: patients take 4cc distilled water

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital

Full name of responsible person

Farhad Hasanvand

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Felezi bridge, Motahari ave

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8177781771

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaghayegh haghju

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Reza Shetabi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available