

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Survey of effect of intravenous granisetron on attenuation of hemodynamic responses of spinal anesthesia in patients undergoing elective caesarian section

Protocol summary

Summary

Due to the role of serotonin in onset of symptoms of anesthesia, serotonin blockers like Ondansetron and Granisetron are taken into consideration to reduce this side effects. To data Granisetron effect on reducing hypotension and bradycardia that caused by spinal block has not been evaluated. In this study we will assess the effect of intravenous Granisetron to reduction of hemodynamic changes due to spinal anesthesia. Sample size is 48 pregnant women. The process will be allocation of the patients to two control and intervention groups and receiving 3 ml normal saline by control group and 3 ml intravenously Gransitron by intervention group. Then systolic and diastolic blood pressure and heart rate will be measured in specific times and finally two groups will be compared. The study will be double blinded (patients and researchers)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411265140N15**

Registration date: **2015-04-12, 1394/01/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-12, 1394/01/23

Registrant information

Name

Omid Azimaraghi

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Science

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of effect of intravenous granisetron on attenuation of hemodynamic responses of spinal anesthesia in patients undergoing elective caesarian section

Public title

Attenuation of anesthesia changes in patients undergoing elective caesarian section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All patients who refer to elective cesarean in Shariati hospital; patients with I or II grade of ASA. Exclusion criteria; patients with Contra indications block subarachnoid; patients with increased sensitivity to Gransytrvn or drugs of local anesthetics; patients with

pregnancy induced hypertension ; patients with inadequate cardiovascular, patients who receiving SSRI or drugs for migraine; the presence of any systemic disease in pregnant; cigarette smokers; alcohol users; patients taking any medication other than prenatal supplements contain iron, folic acid and multivitamins.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 48

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

Ethic committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina Ave, North Karghar, Enghelab Sq, Tehran

City

Tehran

Postal code

Approval date

2014-12-21, 1393/09/30

Ethics committee reference number

2189/130/92/5

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

O29.4

ICD-10 code description

Spinal and epidural anaesthesia-induced headache

during pregnancy

Primary outcomes

1

Description

Heartbeat

Timepoint

In the 2-minute intervals up to 20 minutes and then in 5 - minute intervals until the end of surgery

Method of measurement

Existing equipment in hospital

2

Description

Systolic and diastolic blood pressure

Timepoint

In the 2-minute intervals up to 20 minutes and then in 5 - minute intervals until the end of surgery

Method of measurement

Existing equipment in hospital

3

Description

SPO2

Timepoint

In the 2-minute intervals up to 20 minutes and then in 5 - minute intervals until the end of surgery

Method of measurement

Existing equipment in hospital

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:3 ml Granisetron will prescribe intravenously 5 min before spinal block.

Category

Placebo

2

Description

Control group: 3 ml of normal saline will prescribe 5 minutes before spinal block.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Tehran University of
Medical sciences
Full name of responsible person
Masoud Younesian
Street address
Tehran University of Medical Sciences, Poursina Ave,
Enghelab Sq, North Kargar
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Tehran

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 of Tehran 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

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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