

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Efficacy of intravenous ondansetron in preventing hypotension in patients undergoing elective cesarean section

Protocol summary

Summary

The aim of this randomized triple blind clinical trial is prevention of hemodynamic instability with IV ondansetron in spinal Anesthesia in Cesarean section. 80 pregnant woman (18 to 35 years- old) who had singleton term pregnancies in class I physical health classification of the American society of Anesthesia and were candidate for elective cesarean section with spinal anesthesia entered the study. Mothers with a history of hypertension, diabetes, cardiovascular and cerebral diseases, psychosomatic Disorder, known fetal anomaly, any kind of contraindications for spinal anesthesia were excluded. Mothers with weight more than 100 kg or height less than 150 cm were also excluded. Using random numbers table, mothers were divided into two groups. For All the mothers, 500 cc of Ringer or NS Serum infused before Spinal anesthesia (in group one, 4 mg ondansetron Injected through IV line and in group two, same volume of placebo (instilled water) was injected. Then mothers received 10 mg of bupivacaine 0.5% intrathecally after Spinal anesthesia. HR and BP were measured every 2 min and compared in two groups. Also vomiting and Nausea in two groups were evaluated and compared. Total dose of Atropine and ephedrine in mothers and PH, lactate, Base Excess and Apgar in neonate were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706015381N12**

Registration date: **2017-06-21, 1396/03/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name

Nadia Banihashem

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22 38296

Email address

nbanihashem@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chacellor research for Babol University Of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of intravenous ondansetron in preventing hypotension in patients undergoing elective cesarean section

Public title

The Effect Of Ondansetron on maternal hypotension prevention during elective cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Pregnant women (18 to 35 years old)
 Candidate for elective cesarean section, In class I
 physical health classification of the American Society of
 Anesthesia. All women had singleton term pregnancies.
 Exclusion Criteria: Mothers with a history of
 hypertension; Diabetes; cardiovascular and cerebral
 diseases; known fetal anomaly; any kind of
 contraindications for spinal anesthesia; psychosomatic
 Disorder; Patients weighting over 100 Kg and Height less
 than 150 cm and those with difficult tracheal intubation

Age
 From **18 years** old to **35 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Triple blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 All Patients by using random numbers, they were divided
 into two groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University Of Medical
 Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz
 Street, Babol

City

Babol

Postal code

Approval date

2017-01-09, 1395/10/20

Ethics committee reference number

MUBABOL.REC.1395.148

Health conditions studied

1

Description of health condition studied

Maternal hypotension

ICD-10 code

O26.5

ICD-10 code description

Maternal hypotension syndrome

Primary outcomes

1

Description

Maternal blood presure

Timepoint

Maternal blood pressure was monitored and recorded
 every two minutes for the first 15 minutes following
 spinal anesthesia, and then every 5 minutes until
 completion of surgery.

Method of measurement

Non invasive blood presure cuff

Secondary outcomes

1

Description

Maternal heart rate

Timepoint

during surgery

Method of measurement

With cardiac monitoring and heart rate

2

Description

Neonatal arterial blood gas

Timepoint

After Surgery

Method of measurement

Arterial blood gas samples

3

Description

Neonatal apgar score

Timepoint

1 and 5 minutes after surgery.

Method of measurement

Cheklist/ examination/ observation

Intervention groups

1

Description

Control group: 2 mm distilled water was injected
 intravenously before spinal anesthesia

Category

Prevention

2

Description

Intervention group: 4 mg ondansetron (Norman/Italy) was injected intravenously before spinal anesthesia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani Hospital of Babol

Full name of responsible person

Dr Nadia Banihashem

Street address

Rouhani Hospital, Ganjafrooz Street, Babol

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor research for Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Moghadamnia

Street address

Babol University Of Medical Sciences, Ganjafrooz street, Babol

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor research for Babol 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

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Nadia Banihashem

Position

Associated Professor of Anesthesiology

Other areas of specialty/work

Street address

Rouhani Hospital, Ganjafrooz Street, Babol

City

Babol

Postal code

Phone

+98 11 3223 8284

Fax

Email

nbanihashem@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University Of Medical Sciences

Full name of responsible person

Dr.Nadia Banihashem

Position

Associated Professor of Anesthesiology

Other areas of specialty/work

Street address

Rouhani Hospital, Ganjafrooz Street, Babol

City

Babol

Postal code

Phone

+98 11 3223 8284

Fax

Email

nbanihashem@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University Of Medical Sciences

Full name of responsible person

Dr. Nadia Banihashem

Position

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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