

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparison of various bolus doses of intravenous oxytocin on intraoperative hemodynamic changes and drug side effects in elective cesarean section under spinal anesthesia

Protocol summary

Summary

Purpose: Comparing the effects of various bolus doses of oxytocin after delivery on hemodynamic changes and drug side effects in elective cesarean section. Inclusion criteria: Healthy pregnant women without any underlying disease who have been planned to undergo elective cesarean section to give birth to a single live newborn. Exclusion criteria: 1) failed spinal anesthesia and need to general anesthesia 2) block level higher than T4 3) atonia of uterine 4) surgical complication leading to sever & acute bleeding 5) duration of surgery more than 1 hour 6) administration any uterotonic drug d 7) blood transfusion 8) macrosomia 9) polyhydroamnious. Method: a clinical trial on 120 elective cesarean section. The study is explained for the patients and written consent is obtained. A peripheral blood sample was taken at the preoperative visit to determine hemoglobin level. After spinal anesthesia and giving birth to baby by cesarean section infusion of 20 units of oxytocin in 1 liter of normal saline is started at a rate of 10 ml per minute. At the same time in group 1ml placebo bolus, in group 2 , 2 unit oxytocin bolus and in group 3 , 5 unit oxytocin bolus is administered. Hemodynamic parameters are measured before and 1,3,5,10 minutes after oxytocin and at the end of operation. At the end of surgery we ask the patient about headache and vomiting. Hemoglobin level is checked again after 24 hours of the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112138391N1**
Registration date: **2012-01-07, 1390/10/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-07, 1390/10/17

Registrant information

Name

Mehrsima Abdollahzadeh

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 2021

Email address

abdollahzadeh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gilan University of Medical Sciences

Expected recruitment start date

2010-12-12, 1389/09/21

Expected recruitment end date

2011-12-12, 1390/09/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of various bolus doses of intravenous oxytocin on intraoperative hemodynamic changes and drug side effects in elective cesarean section under spinal anesthesia

Public title

A comparison of various bolus doses of intravenous oxytocin on intraoperative hemodynamic changes in elective cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy pregnant women without any underlying disease who have been planned to undergo elective cesarean section to give birth to a single live newborn. Exclusion criteria included: 1) failure of spinal anesthesia and need to general anesthesia; 2) block level higher than T4; 3) atonia of uterine during or after surgery; 4) surgical complication leading to severe & acute bleeding; 5) duration of surgery more than 1 hour; 6) administration any uterotonic drug during or after surgery; 7) need to blood transfusion during & after transfusion; 8) macrosomia; 9) polyhydramnios.

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Vice chancellor for research, Gilan University of Medical Sciences

Street address

Namjoo street

City

Rasht

Postal code

Approval date

2010-12-11, 1389/09/20

Ethics committee reference number

1891193707

Health conditions studied

1

Description of health condition studied

obstetric conditions

ICD-10 code

O94

ICD-10 code description

Sequelae of complication of pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Survey hemodynamic changes

Timepoint

Before drug administration & 1min, 3min, 5min & 10 min

Method of measurement

Manual manometer & stethoscope & digital monitoring

Secondary outcomes

1

Description

Blood hemoglobin

Timepoint

Before & 24 hours after surgery

Method of measurement

H1 automatic device

2

Description

Headache

Timepoint

During surgery, after prescription

Method of measurement

Asking patient

3

Description

Vomiting

Timepoint

During surgery, after prescription

Method of measurement

Asking patient

Intervention groups

1

Description

prescription of 1ml water for injection in addition of infusion of oxytocin after delivery during cesarean section in control group

Category

Placebo

2

Description

prescription of 2 units oxytocin bolus in addition of infusion of this drug after delivery during cesarean section in intervention group

Category

Treatment - Drugs

3

Description

prescription of 5 units oxytocin bolus in addition of infusion of this drug after delivery during cesarean section in intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital, Rasht

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abdollahzadeh, Mehrsima MD

Full name of responsible person

Abdollahzadeh, Mehrsima MD

Street address

Reproductive Health research center, Alzahra hospital, Namjo street

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Abdollahzadeh, Mehrsima MD

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

Guilan University of Medical Sciences

Full name of responsible person

Abdollahzadeh, Mehrsima MD

Position

Assistant professor of Guilan University of Medical Sciences

Other areas of specialty/work

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Reproductive Health Research Center, Alzahra hospital, Namjo street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Abdollahzadeh, Mehrsima MD

Position

Assistant professor of Guilan University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

Position

B.S Midfiwe

Other areas of specialty/work

Street address

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Rasht

Postal code**Phone****Fax****Email**

h_fertility@gums.ac.ir

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