

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the effects of Oxytocin and Methylergonovine in elective caesarean section under spinal anesthesia

Protocol summary

Summary

The purpose of this study is comparison the effects of oxytocin and methylergonovine in caesarean section under spinal anesthesia. This study is designed as a randomized, prospective, interventional and single blind clinical trial. The study population is all the parturients who are candidate for elective caesarean section under spinal anesthesia. Inclusion criteria consist of: Elective caesarean section . Exclusion criteria consist of: Positive history of cardiovascular disease; Positive history of preeclampsia; Emergent caesarean section; Factors increasing risk of uterine atony . In this study 80 patients are selected and 40 patients in one groups are considered. One group of patients is received 0.2 mg methylergonovine in 1 liter isotonic serum infused after delivery of fetus . Another group of patients is received 30 unit oxytocin in 1 liter isotonic serum infused after delivery of fetus. All the patients after spinal anesthesia in supine position will be monitored and systolic blood pressure; diastolic blood pressure; heart rate and mean arterial blood pressure are recorded in minutes 1,3,5 after spinal anesthesia .Also systolic blood pressure; diastolic blood pressure; heart rate and mean arterial blood pressure are recorded in minutes 1,3,5,10,15,20 after drug administration. Amount of bleeding are estimated by volume of bottle of suctioning apparatus and field of surgery. Hemodynamic parameters are recorded in minutes 5,10,15,20,30 in recovery room.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207055751N3**

Registration date: **2012-07-19, 1391/04/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-19, 1391/04/29

Registrant information

Name

Abdolrasoul Anvaripour

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 1252 6801

Email address

anvari@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-07-31, 1391/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of Oxytocin and Methylergonovine in elective caesarean section under spinal anesthesia

Public title

Comparison the effects of uterotonic constrictors in caesarean section under spinal anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria consist of: Elective caesarean section
Exclusion criteria consist of: positive history of cardiovascular disease; positive history of preeclampsia; emergent caesarean section; factors increasing risk of uterine atony

Age

From **18 years** old to **40 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bushehr University of Medical Sciences

Street address

Bahmani; pardis site; Bushehr University of Medical Sciences

City

Bushehr

Postal code

Approval date

2012-04-11, 1391/01/23

Ethics committee reference number

5351

Health conditions studied

1

Description of health condition studied

Caesarean section

ICD-10 code

082.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Systolic Blood Pressure

Timepoint

In minutes 1,3,5 after spinal anesthesia and in minutes 1,3,5,10,15,20 after drug administration

Method of measurement

Non Invasive Blood Pressure Monitoring

2

Description

Diastolic Blood Pressure

Timepoint

In minutes 1,3,5 after spinal anesthesia and in minutes 1,3,5,10,15,20 after drug administration

Method of measurement

NonInvasive Blood Pressure Monitoring

3

Description

Heart Rate

Timepoint

In minutes 1,3,5 after spinal anesthesia and in minutes 1,3,5,10,15,20 after drug administration

Method of measurement

Non Invasive Blood Pressure Monitoring

4

Description

Mean Arterial Blood Pressure

Timepoint

In minutes 1,3,5 after spinal anesthesia and in minutes 1,3,5,10,15,20 after drug administration

Method of measurement

Non Invasive Blood Pressure Monitoring

Secondary outcomes

1

Description

Amount of bleeding after drug administration

Timepoint

In operation room and recovery room

Method of measurement

Suctioned blood volume in bottle and field of surgery

2

Description

Time of uterine atony

Timepoint

After fetus delivery

Method of measurement

Taking the time of delivery of fetus up to uterine contraction

Intervention groups

1

Description

Intervention Name: Methylergonovine Intervention
Description: After fetus delivery , 0.2mg
Methylergonovine in 1 liter isotonic serum in case group
will be infusion

Category

Treatment - Drugs

2

Description

In control group: Oxytocin 30 unit in one liter isotonic
serum will be infused after fetus delivery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bentolhoda Hospital

Full name of responsible person

Abdolrasoul Anvaripour

Street address

Bentolhoda Hospital; Moalem Street

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Mahnoosh Khakzad

Street address

Bahmani; Pardis Site; Bushehr University of Medical
Sciences

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bushehr 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

Bushehr University of Medical Sciences

Full name of responsible person

Abdolrasoul Anvaripour

Position

Assistant Prifessor of Cardiac Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Abdolrasoul Anvaripour

Position

Assistant Professor of Cardiac Anesthesiology

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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