

# 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

#### Street address

Reproductive Health Research Center, Alzahra hospital, Namjo street

#### City

Rasht

#### Postal code

#### Phone

+98 13 1322 5624

#### Fax

#### Email

abdollahzadeh@gums.ac.ir

#### Web page address

## Person responsible for scientific 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

#### Street address

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#### Web page address

## 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

Reproductive Health research center, Alzahra hospital, Namjo street

**City**

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*