

# Oxytocin dose effects during cesarean section

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
02/10/2019	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
03/10/2019	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
03/10/2019	Pregnancy and Childbirth	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

To conduct a comparative study of the effect of oxytocin dose on heart activity (ST-segment depression), during the operation, cesarean section under spinal anesthesia.

### Who can participate?

Women aged 15 - 25 with singleton pregnancy undergoing an elective cesarean section

### What does the study involve?

Participants will be randomised to receive one of two different doses of oxytocin during childbirth. The blood pressure and heart activity will be monitored.

### What are the possible benefits and risks of participating?

There are no possible advantages and risks of participation

### Where is the study run from?

Autonomous Public Health Care Institution of Amur Region "Amur Regional Clinical Hospital", Regional Perinatal Center, Russia

### When is the study starting and how long is it expected to run for?

October 2016 to September 2018

### Who is funding the study?

Autonomous Public Health Care Institution of Amur Region "Amur Regional Clinical Hospital", Regional Perinatal Center, Russia

### Who is the main contact?

Evgeny Degtyaryov  
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## Contact information

### Type(s)

Public

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

1

## Study information

**Scientific Title**

Oxytocin dose effects on ST segment changes, arterial hypotension and blood loss volume in parturients of different ages during cesarean section

**Study objectives**

Oxytocin (OT) is a first-line treatment for post-delivery bleeding prevention and treatment, but it is known to provide a range of other effects: parasympathetic neuromodulation, vasodilation, negative inotropic and chronotropic effects as a consequence of blood pressure (BP) drop. The hemodynamic effects of different dose of oxytocin and its influence on myocardium in different types of parturients remain unresolved. This prospective study was planned to assess the influence of the different dose of oxytocin on myocardial damage during cesarean section in primiparas of different ages.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 21/09/2016, Ethics Committee of the Autonomous Public Health Care Institution of Amur Region "Amur Regional Clinical Hospital" (Russia, 675006, Amur region, Blagoveshchensk, Gorky str., 95, Scientific Department; +8 (4162) 319 - 032; science.prorektor@AmurSMA.su), ref: n/a

**Study design**

Interventional randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Control of bleeding during cesarean section

**Interventions**

All patients were randomized into 2 arms according to OT dosing given by various clinical guidelines: 5 IU and 10 IU. The rate of intravenous drip of oxytocin in all puerperas was equal to 0.5 IU/min. the Introduction of additional doses of OR other drugs with uterotonic effect was not carried out.

Arterial hypotension was noted as systolic blood pressure below 80 mm Hg, lasted less than 5 min. and was controlled with IV microfluidic infusion of noradrenalin solution with the rate of 0.03 µg/kg/min.

ST-segment status was analyzed using BeneView T6 patient monitor (Mindray, China). Clinically significant ST-segment depression was reported if ST fell more than 0.5 mm below the isoelectric line. ST-segment depression was reversible and did not last more than 15 min. All patients were randomized into 2 arms according to oxytocin dosing given by various clinical guidelines: 5 IU and 10 IU.

The surgeon assessed oxytocin uterotonic effects via palpation during cesarean section and within 2 hours afterwards.

Randomization algorithm included patient randomization into 2 arms using a random number generator and closed envelope method. Also in each randomized arm patients were stratified by age into 2 subgroups: young patients (below 18) and ones of optimal reproductive age (18 years and older).

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Oxytocin

**Primary outcome(s)**

1. Intraoperative ST segment depression measured using intraoperative ECG monitoring (II standard lead), ST segment depression (mm); ST segment status was analyzed using BeneView T6 patient monitor (Mindray, China).
2. Intraoperative hypotension: Arterial hypotension was noted as systolic blood pressure below 80 mm Hg, lasted less than 5 min. and was controlled with IV microfluidic infusion of noradrenalin solution with the rate of 0.03 µg/kg/min.

## **Key secondary outcome(s)**

Intraoperative blood loss was determined using indirect visual method by a team of MD's, which included: a surgeon (obstetrician-gynecologist, highest Qualification Grade), an assistant surgeon and an anesthesiologist-intensivist (highest Qualification Grade).

## **Completion date**

30/11/2018

## **Eligibility**

### **Key inclusion criteria**

1. Full-term singleton pregnancy
2. Elective cesarean section
3. Age of 15 to 25 years inclusive
4. Body mass index (BMI) below 25 kg/m<sup>2</sup>
5. Pregnancy and labor parity - 1

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

Female

### **Total final enrolment**

45

### **Key exclusion criteria**

1. Severe extragenital diseases
2. Preeclampsia and eclampsia

### **Date of first enrolment**

01/10/2016

### **Date of final enrolment**

30/09/2018

## **Locations**

### **Countries of recruitment**

Russian Federation

### **Study participating centre**

Autonomous Public Health Care Institution of Amur Region "Amur Regional Clinical Hospital",  
Regional Perinatal Center  
Voronkova str. 26  
Blagoveshchensk  
Russian Federation  
675000

## Sponsor information

### Organisation

Federal state budget educational institution higher education «Amur State Medical Academy» of the Ministry of Health of the Russian Federation.

### ROR

<https://ror.org/05x21mt76>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Autonomous Public Health Care Institution of Amur Region "Amur Regional Clinical Hospital",  
Regional Perinatal Center

## Results and Publications

### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes