

Oxytocin dose effects during cesarean section

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

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Contact information

Type(s)

Public

Contact name

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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).

Overall study start date

21/09/2016

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/m²
5. Pregnancy and labor parity - 1

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Female

Target number of participants

45

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

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Russian Federation

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Sponsor information

Organisation

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

Sponsor details

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Sponsor type

University/education

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

Publication and dissemination plan

PLOS ONE

Intention to publish date

01/03/2020

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