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Oxytocin dose effects during cesarean section

Submission date	Recruitment status	[ ] Prospectively registered
02/10/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/10/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/10/2019	Pregnancy and Childbirth	[ ] 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

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Additional identifiers

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.prorector@AmurSMA.su), ref: n/a

Primary study design
Interventional

Study design
Interventional randomised controlled trial

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/m²
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