ISRCTN17860978 https://doi.org/10.1186/ISRCTN17860978

Effects of anaesthesia and oxytocin on maternal vascular tone

Submission date
14/03/2018

Recruitment status
No longer recruiting

Registration date
16/05/2018

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Oxytocin is a drug routinely used in women to induce contraction of the uterus and prevent bleeding after childbirth. However it has side effects on the blood pressure and the heart which in some patients could lead to serious events.
This study aims to further investigate the effects of oxytocin on the human heart and blood vessels.
Who can participate?
Women aged 18 and over scheduled for termination of pregnancy in first trimester

What does the study involve?
Participants are randomly assigned to one of two groups. Those in the first group receive Oxytocin injections either early or late during the medical abortion, whilst under general anaesthetic. Those in the second group receive a placebo (dummy) injection either early or late during the medical abortion, whilst under general anaesthetic.
Participants are monitored using a pain-free device that analyses the pulse wave (change in blood volume as the heart contracts) in the finger, and a system that monitors blood pressure, heart rate and heart activity during the anaesthetic.

What are the possible benefits and risks of participating?
Participants may benefit from further knowledge about the cardiovascular effects of oxytocin in a clinical setting. The study protocol does not differ from standard clinical procedure, except randomization and further non-invasive, non-painful monitoring.

Where is the study run from?
Skåne University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
August 2012 – January 2017

Who is funding the study?
1. Lund University (Sweden)
2. Region Skåne (Sweden)

Who is the main contact?
Professor Per Olofsson (Scientific)
per.olofsson@med.lu.se

Contact information

Type(s)
Scientific

Contact name
Prof Per Olofsson

ORCID ID
http://orcid.org/0000-0001-7840-525X

Contact details
Lund University
Box 117
Lund
Sweden
22100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Effects of oxytocin and anaesthesia on vascular tone in pregnant women: a randomised double-blind placebo-controlled study using non-invasive pulse wave analysis

Study objectives
Oxytocin decreases vascular tone and elevates cardiac output in first trimester pregnacy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Research Ethics Committee in Lund, 13/12/2012, ref: 2012/649

Study design

Randomised double-blind placebo-controlled single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional file (in Swedish)

Health condition(s) or problem(s) studied
Vascular tone and hemodynamic change in pregnancy

Interventions
Participants are randomised by a web-based random number generator to a treatment or placebo group. Those in the treatment group receive 8.3 µg (5 U) Oxytocin by injection during the first trimester surgical evacuation of the gravid uterus under general anaesthesia. Those in the control group receive a placebo injection. The injections are administered once either early or late in the procedure, in a double-blind fashion.
The effects of oxytocin on the heart and the vascular tree are assessed using digital photoplethysmography pulse wave analysis (DPA) variables. The Meridian DPA (TM) works through an infra-red light emitting diode and receiver, measuring light absorption through the finger. The pulse wave through the finger augments the light absorption, and computer analysis generates a pulse volume curve. From the analysis of the waveform of this curve, hemodynamic estimates are computed and presented as 17 different variables. Some of these are shown to have the best repeatability, these are used in this study.
Also, heart rate, mean arterial blood pressure and electrocardiographic ST index are recorded. These variables are noted before and after induction of anaesthesia and 1 minute after each injection. No further follow up. DPA variables together with the other variables make it possible to assess the LV ejection function and vascular tone, possibly differentiating between that of large or small arteries.

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
Oxytocin, Propofol

Primary outcome measure
The effect of oxytocin on vascular tone and cardiac LV ejection fraction is assessed using digital photoplethysmography pulse wave analysis (DPA) variables before and 1 minute after each injection.

Secondary outcome measures

The effect of anaesthesia on vascular tone and cardiac LV ejection fraction is assessed by digital photoplethysmography pulse wave analysis (DPA) variables before and after induction of anaesthesia.

Overall study start date
01/08/2012

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. Women
2. Aged 18 years and over
3. Scheduled for termination of pregnancy in the first trimester by vacuum aspiration or curettage

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
51

Total final enrolment
51

Key exclusion criteria
1.Gestational age above 12 weeks in viable pregnancies
2. Age less than 18 years
3. Do not understand Swedish
4. Serious cardiovascular disorders.

Date of first enrolment
01/01/2013

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital
Malmö
Sweden
20502

Sponsor information

Organisation
Lund University

Sponsor details
Box 117
Lund
Sweden
22100
+46 46 222 0000
lu@lu.se

Sponsor type
University/education

Website
https://www.lu.se/

Organisation
Skåne University Hospital

Sponsor details
Diarium
Rådhus Skåne
Kristianstad
Sweden
29189
+46 40 331 000
region@skane.se

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Lunds Universitet

Alternative Name(s)
Lund University, Universitas Lundensis, Universitas Gothorum Carolina, Royal Caroline Academy, Regia Academia Carolina, Lund University | Lund, Sweden | LU, Lunds universitet, LU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
Region Skåne

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sofus Rabow (sofus.rabow@med.lu.se)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		26/03/2018	01/04/2019	No	Yes
Participant information sheet		26/03/2018	01/04/2019	No	Yes
Results article	results	22/11/2018	23/11/2020	Yes	No