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Continuous Controllable Balloon Dilation (CCBD): a novel approach for cervix dilation

Submission date
13/06/2011

Recruitment status
No longer recruiting

Registration date
21/06/2011

Overall study status
Completed

Last Edited
26/10/2017

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
Cervical dilation is the opening of the cervix, the entrance to the uterus (womb), for example during childbirth. Cervical dilation with mechanical dilators is connected with various complications like infection and bleeding. In order to achieve safe and painless cervical dilation, a new medical device has been constructed, called Continuous Controllable Balloon Dilation (CCBD), where controlled pumping of incompressible fluid into a specially constructed balloon dilator leads to continuous dilation of the cervical canal. The aim of this study is to find out whether the dilation by means of the CCBD is less damaging to the cervical canal than traditional mechanical dilation devices.

Who can participate?
Pregnant women aged from 19 to 40

What does the study involve?
Participants are randomly allocated into three groups. Group 1 do not undergo dilation, in group 2 the dilations are performed using mechanical dilators, and in group 3 the dilations are performed using CCBD. Tissue samples are obtained from the cervix to assess cervical damage before and after dilation.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Clinical Center of Montenegro

When is the study starting and how long is it expected to run for?
September 2001 to September 2011

Who is funding the study?
AUDIOTEL d.o.o. Belgrade (Serbia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EP1299146

Study information

Scientific Title
Comparative analysis of the damage of the cervical canal during the dilation of the cervix by means of classical and hydraulic dilators

Acronym
CCBD

Study objectives
The main purpose of this research is to assess that the dilation by means of the hydraulic dilator is much less damaging to the cervical canal than the classical alternative, which is more commonly performed and by use of the Hegar dilators.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of Clinical Center of Montenegro, 28/01/2010

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cervical dilation

Interventions
This study was carried out in order to enable analysis of the results of CCBD application for cervix dilation in comparison with a representative of traditional mechanical dilation devices (HeD)
Group I (without dilations)
Group II (the dilations were performed by HeD)
Group III (the dilations were performed by CCBD)

CCBD is a fully controllable device for cervical dilation based on the use of a specially constructed balloon dilator (BD) which consists of three layers: inner silicone layer, central layer made from high strength fabric, and outer silicone layer. The maximum diameter of BD expansion is limited by the central layer. The outer silicone layer is in contact with the tissues of the cervix during the dilation process. This BD was tested on consistency and endurance at a pressure of 25 bars, without detected risk of breakage. The reliability of CCBD was confirmed in vitro and in vivo.

The whole dilation procedure using CCBD is performed continuously with just one dilator placement. For the purpose of this study CCBD was integrated in a system that enables real time data acquisition and monitoring of relevant parameters related to the biophysics of the dilation process. Dilation dynamics directly depend on the flow of an incompressible fluid to the BD which is an easily controllable parameter. As an incompressible working fluid, distilled water was used with the addition of non-ionic contrast medium (Ultravist-300, Schering AG). This enables the possibility for visual monitoring of the dilation process on Digital Subtraction Apparatus for angiography (DSA).

Tissue material for histology evaluation of cervical damage was obtained from endocervical mucosa by single curettage (Novacs sonde was used) before and after dilation by HeD or CCBD.

Samples were stained by haematoxylin-eosin (H&E) and analysed by the light microscope Olympus BX 51. Cervical tissue sections, stained with H&E, were examined under a low-power (100×) light microscope (Zeiss Axioskop 40, Jena, Germany) equipped with digital camera. Images were captured and the surface areas of the regions under haemorrhagia were measured using Autodesk AutoCAD 2009 software application for design and drafting.

Intervention Type
Device

Primary outcome measure
Tissue material for histology evaluation of cervical damage:
1. Epithelium damage (grade 0, 1, 2)
2. Basal membrane damage (grade 0, 1)
3. Stromal damage (grade 0, 1)
4. Cervical haemorrhagia (grade 0, 1, 2, 3)

Secondary outcome measures
Semi-quantitative determination of tissue haemorrhagia

Overall study start date
01/09/2001

Completion date
01/09/2011

Eligibility

Key inclusion criteria
1. Age from 19 to 40
2. Pregnancy verified by an ultrasound
3. Singleton pregnancy
4. Gestational age of 10 weeks or less (determined by the date of the last menstruation and verified by an ultrasound)
5. Uterus and cervix with normal findings
6. Absence of uterine contractions or bleeding
7. Cervix uteri maintained in full, external wall closed

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Key exclusion criteria

1. Signs of spontaneous abortion (presence of the uterine bleeding, uterine contractions, with or without alteration of the cervix)
2. Former attempt of an abortion or usage of substances for cervical maturation
3. Multiple pregnancy
4. Presence or at least suspicion of a septic abortion, followed by increased body temperature of 38 degree celsius or higher, painful uterus and smelly vaginal secretion
5. Presence of any kind of former intervention on the uterine cervix
6. Uterine or cervical anomalies
7. Intra-uterine device in situ
8. Haemorrhagic diseases
9. Chronic diseases

Date of first enrolment
01/09/2001

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
Montenegro

Study participating centre
Clinical Center of Montenegro
Podgorica
Montenegro
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Sponsor information

Organisation
Clinical Center of Montenegro (Montenegro)

Sponsor details
c/o Vukcevic Gordana
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
AUDIOTEL d.o.o. Belgrade, Serbia

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/06/2000		Yes	No
Results article	results	22/10/2012		Yes	No