

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

Submission date 13/06/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/06/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/10/2017	Condition category Pregnancy and Childbirth	☐ 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?

Dr Gordana Vukcevic

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Interventional randomised controlled trial

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

Semi-quantitative determination of tissue haemorrhagia

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

81000

Sponsor information

Organisation

Clinical Center of Montenegro (Montenegro)

Funder(s)

Funder type

Other

Funder Name

AUDIOTEL d.o.o. Belgrade, Serbia

Results and Publications

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