ISRCTN30949871 https://doi.org/10.1186/ISRCTN30949871

Cervical resistance during balloon dilatation

Submission date
30/04/2015

Recruitment status
No longer recruiting

Registration date
13/05/2015

Overall study status
Completed

Last Edited
30/10/2015

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Cervical dilatation is the term used to describe the opening of the cervix (entrance to the womb (uterus)). Cervical dilatation can occur naturally, such as during childbirth and miscarriage, or it can be caused by surgical or medical procedures, such as during a pregnancy termination (abortion). There are various mechanical devices available for surgeons or clinicians to use to open the cervix, however some of these devices carry a risk of causing complications, such as damage to the cervix or uterus. Hydraulic dilatation is an alternative method to open the cervix. This involves opening the cervix with a balloon placed within the cervix. Fluid is pumped into the balloon causing it to gently expand. The balloon's expansion is controlled by a computer software system designed to provide continuous and controllable balloon dilatation (CCBD). The aim of this study is to test a new system for CCBD, which consists of a computer programmed hydrostatic pump connected to a balloon extension. This new CCBD method aims to measure and determine the strength of muscles within the cervix (cervical resistance), and also the location of cervical resistance, by placing two pressure-measuring films on the top and on the bottom of the balloon extension. This new system will be tested in women seeking a surgical abortion (vacuum aspiration).

Who can participate?
Pregnant women who have been pregnant for less than 10 weeks.

What does the study involve?
All participants have the new system for hydraulic dilatation during the abortion procedure.

What are the possible benefits and risks of participating?
The intervention is considered to be completely risk free and thus, beneficial for the patient.

Where is the study run from?
Clinical Center Kragujevac (Serbia)

When is the study starting and how long is it expected to run for?
May 2013 to September 2013

Who is funding the study?
Ministry of Education, Science and Technological Development (Serbia)

Who is the main contact?
Dr P Arsenijevic

Study website
http://www.iii41007.fink.rs/index.php?option=com_content&view=article&id=50&Itemid=57

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
III 41007

Study information

Scientific Title
Analysis of cervical resistance during continuous controllable balloon dilatation

Study objectives
Cervical resistance during continuous controllable dilatation is highest in the zone of the internal orifice of the uterus (inner cervical os); the uterine cervix behaves as a sphincter during continuous controllable balloon dilatation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Clinical Center Kragujevac, Serbia, 16/04/2013, ref: 01-4169.

Study design
Prospective experimental randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Cervical resistance during continuous controllable balloon dilatation prior to termination of unwanted pregnancy.

Interventions
To measure and determine the location of cervical resistance: an improved system for continuous and controllable balloon dilatation (CCBD) (a programmed hydrostatic pump connected to a balloon extension) will be used. CCBD uses two pressure-measuring films on the top and on the bottom of the balloon extension. The dilation process is analysed using Dilation Controller software. The software monitors the dilation process in real time and controls the given mode of dilation.

Intervention Type
Device

Primary outcome measure
To precisely measure, analyse and map the cervical canal during dilatation of the uterine cervix, and locate every point of resistance along the upper and lower sides of the cervical canal.

Secondary outcome measures
1. Association between values of cervical resistance and the number of previous miscarriages
2. Association between the values of cervical breaking point and number of previous miscarriages

Overall study start date
01/05/2013

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Age 18-40
2. Pregnancy verified by an ultrasound
3. Singleton pregnancy
4. Gestational age of 10 weeks or less
5. Absence of uterine bleeding or cramping
6. Cervix and uterus without pathological changes
7. Closed external cervical os

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
42

Key exclusion criteria
1. Any previous attempt at an abortion or use of substances for cervical maturation
2. Multiple pregnancy
3. Presence or, at minimum, the suspicion of a septic abortion, followed by an elevated body temperature of 38°C or higher, uterine pain and odorous vaginal secretions.
4. Presence of any previous intervention performed on the uterine cervix
5. Uterine or cervical anomalies
6. Intrauterine device in situ
7. Hemorrhagic and/or chronic diseases

Date of first enrolment
01/05/2013

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Serbia

Study participating centre
Clinical Center Kragujevac
22 Zmaj Jovina Street
Kragujevac
Serbia
34000

Sponsor information

Organisation
Ministry of Education, Science and Technological Development (Serbia)

Sponsor details
Nemanjina street 22-26
Belgrade
Serbia
11000

Sponsor type
Government

Website
http://www.iii41007.fink.rs/index.php?option=com_jresearch&view=project&task=show&id=1&Itemid=63

ROR
https://ror.org/01znas443

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Science and Technological Development (Serbia)

Results and Publications

Publication and dissemination plan
The results and conclusions of the study will be disseminated through scientific articles, scientific books, presentations and congress seminars. One article is about analysis of the cervical resistance measured by pressure sensitive films and is intended to be published by the

end of this year. Another article is about sphincter qualities of the uterine cervix and is intended to be published by the end of this year.

Intention to publish date
12/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/10/2015		Yes	No