

# Cervical resistance during balloon dilatation

<b>Submission date</b> 30/04/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/10/2015	<b>Condition category</b> Other	<input type="checkbox"/> 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](http://www.iii41007.fink.rs/index.php?option=com_content&view=article&id=50&Itemid=57)

## Contact information

**Type(s)**

Scientific

**Contact name**

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34000

## 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](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**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	28/10/2015		Yes	No