

# Effect of local anesthesia on pain sensation during colposcopy

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>05/11/2012   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>05/03/2013 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>24/01/2019       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Traditionally colposcopy [is a procedure where the surface of the cervix is closely examined using a magnifying instrument called a colposcope] with punch biopsies [a biopsy that is performed by using a punch, an instrument for cutting and removing a disk of tissue] is performed without any local anesthesia in Finland. We have observed that using local anesthesia reduces pain and discomfort during this treatment.

### Who can participate?

Any woman who have been referred to diagnostic colposcopy in Helsinki University Hospital. Only if they have allergy to anesthetic agent, if they are pregnant, or if there is a suspicion of cancer they are not asked to participate in this study.

### What does the study involve?

Half of the participants will be randomly allocated to receive local anesthesia before punch biopsies. Other half will be treated without local anesthesia. Pain will be measured by visual analogue scale (VAS). Participants from both groups will be asked to fill in a questionnaire, Beck's anxiety inventory before the treatment.

### What are the possible benefits and risks of participating?

The possible benefit is probably less pain during the punch biopsies.

The only additional risk for participating in the study is possible allergy to anaesthetic agent that the subject is not aware of. All the subjects would be treated the same way despite of participating in the study or not.

### Where is the study run from?

The study takes place in Helsinki University Hospital, Department of Obstetrics and Gynaecology.

### When is the study starting and how long is it expected to run for?

The study started in November, 2012 and will last until May 2013.

### Who is funding the study?

This study has received funding from Helsinki University Research Foundation.

Who is the main contact?

Dr Mari Kiviharju  
mari.kiviharju@hus.fi

## Contact information

### Type(s)

Scientific

### Contact name

Dr Pekka Nieminen

### Contact details

Helsinki University Hospital  
Bo-BOX 140  
Helsinki  
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00029

## Additional identifiers

### Clinical Trials Information System (CTIS)

2012-005106-21

## Study information

### Scientific Title

Effect of local anesthesia on pain sensation during colposcopy: a randomized trial

### Study objectives

The main objective is to measure pain by using visual analogy scale (VAS) during colposcopy and biopsies. We hypothesize that local anesthesia will reduce pain and discomfort.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Helsinki University Institutional Review Board, 2.10.2012, ref: (292/13/03/03/2012)

### Primary study design

Interventional

### Study design

Randomized controlled trial

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Colposcopy: pain during punch biopsies

### **Interventions**

Woman referred to colposcopy will be randomized into two groups

1. Colposcopy with local anesthesia
2. Colposcopy without local anesthesia

Pain will be measured by VAS scale after biopsies. We will also ask Beck's anxiety inventory for both groups before the treatment.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Applicable

### **Primary outcome(s)**

Pain, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain) after punch biopsies.

### **Key secondary outcome(s)**

1. Abnormal bleeding after colposcopy
2. Beck's anxiety inventory score

### **Completion date**

30/05/2013

## **Eligibility**

### **Key inclusion criteria**

All eligible women who have been referred to diagnostic colposcopy for any cytological abnormality

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

1. Allergy to local anesthesia (prilocain + felypressin)
2. Pregnancy
3. Suspicion of cancer

**Date of first enrolment**

12/11/2012

**Date of final enrolment**

30/05/2013

## **Locations**

**Countries of recruitment**

Finland

**Study participating centre**

Helsinki University Hospital

Helsinki

Finland

00029

## **Sponsor information**

**Organisation**

Helsinki University Hospital (Finland)

**ROR**

<https://ror.org/02e8hzf44>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Helsinki University Research Foundation (Finland)

## **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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/04/2017   | 24/01/2019 | Yes            | No              |