

Effect of local anesthesia on pain sensation during colposcopy

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

Type(s)

Scientific

Contact name

Dr Pekka Nieminen

Contact details

Helsinki University Hospital
Bo-BOX 140
Helsinki
Finland
00029

Additional identifiers

EudraCT/CTIS number

2012-005106-21

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Randomized 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 below to request a patient information sheet (in Finnish only)

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 measure

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

Secondary outcome measures

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

Overall study start date

12/11/2012

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

Age group

Adult

Sex

Female

Target number of participants

200

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)

Sponsor details

Bo-BOX 140

Helsinki

Finland
00029

Sponsor type

Hospital/treatment centre

Website

<http://www.med.helsinki.fi>

ROR

<https://ror.org/02e8hzh44>

Funder(s)

Funder type

University/education

Funder Name

Helsinki University Research Foundation (Finland)

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 | 01/04/2017 | 24/01/2019 | Yes | No |