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Effect of local anesthesia on pain sensation during colposcopy

Submission date	Recruitment status	[_] Prospectively registered
05/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/03/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2019	Surgery	

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 Obsterics 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
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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/02e8hzf44

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