ISRCTN53680128 https://doi.org/10.1186/ISRCTN53680128

Colposcopy referral rate can be reduced by high risk human papillomavirus (HPV) triage in the management of low-grade cytological lesions

Submission date 27/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/09/2010	**Overall study status** Completed	
Last Edited 22/09/2010	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-022670-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2010-022670-13

Study information

Scientific Title
Colposcopy referral rate can be reduced by high risk human papillomavirus (HPV) triage in the management of low-grade cytological lesions: a randomised controlled 3-arm trial

Study objectives
To study if colposcopy referrals can be reduced by using repeated pap smear in combination with high risk human papillomavirus (HPV) test in management of low-grade cytological lesions. Hypothesising that a considerable proportion of cervical lesions heal spontaneously we also studied the possibility to perform colposcopy in delayed schedule.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Helsinki Institutional Review Board approved on the 12th May 2005 (ref: 92 /2005; 254/E9/05 [142/E8/05])

Study design
Randomised controlled three-arm 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 (Finnish and Swedish only)

Health condition(s) or problem(s) studied
Cervical intraepithelial neoplasia (CIN)

Interventions
Group A: colposcopy with punch biopsy, pap smear and hrHPV test within 2 - 3 months from referral pap smear.
Group B: same procedures were performed with delayed schedule, within 6 months from referral.
Group C: repeat pap smear and hrHPV test were performed first and colposcopy was offered to only women who were either hrHPV positive, or to those hrHPV negative women who had pap smear LSIL or worse. If women were diagnosed with CIN 2 or worse, she was treated with LLETZ. Also CIN1 lesions were treated with LLETZ among women older than 30 years.

All women had pap smear and hrHPV test in 6 - 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number of hrHPV positives in different study groups
2. Number of high-grade CIN

Assessed at primary colposcopy (Group A at 2 - 3 months from referral pap smear, Group B within 6 months from referral pap smear and Group C at primary colposcopy, within 6 months from referral pap smear) among those women who had colposcopy. Also followed up with pap smear and hrHPV at 6 - 12 months from primary colposcopy visit.

Secondary outcome measures
Number of low-grade CIN (CIN1).

Assessed at primary colposcopy (Group A at 2 - 3 months from referral pap smear, Group B within 6 months from referral pap smear and Group C at primary colposcopy, within 6 months from referral pap smear) among those women who had colposcopy. Also followed up with pap smear and hrHPV at 6 - 12 months from primary colposcopy visit.

Overall study start date
01/05/2005

Completion date
31/05/2009

Eligibility

Key inclusion criteria
1. Female patients aged 16 - 72 years
2. Referred to colposcopy because of low-grade pap smear abnormality (repeated atypical squamous cells of undetermined significance [ASCUS] or low-grade squamous intraepithelial lesion [LSIL])

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
600

Key exclusion criteria
Previous known treatment for cervical intraepithelial neoplasia or cervical cancer

Date of first enrolment
01/05/2005

Date of final enrolment
31/05/2009

Locations

Countries of recruitment
Finland

Study participating centre
BOX 140, 00290 HUS
Helsinki
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00290

Sponsor information

Organisation
Helsinki University Hospital (Finland)

Sponsor details
BO 140
Helsinki
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00290

Sponsor type
Hospital/treatment centre

Website
http://www.hus.fi/?path=59

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Helsinki University Hospital (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