

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

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		<input type="checkbox"/> Results
<b>Last Edited</b> 22/09/2010	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
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

### **Study type(s)**

Treatment

### **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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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)

### ROR

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

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Helsinki University Hospital (Finland)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration