ISRCTN14634238 https://doi.org/10.1186/ISRCTN14634238

# A randomised controlled trial of cytological surveillance versus patient choice between surveillance and colposcopy in managing mildly abnormal cervical smears

**Submission date**
23/01/2004

**Recruitment status**
No longer recruiting

**Registration date**
23/01/2004

**Overall study status**
Completed

**Last Edited**
08/04/2016

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Cervical screening (also known as a smear test) involves a doctor or nurse using a small brush to collect cells from the surface of the cervix (the entrance to the womb from the vagina). Detecting and removing abnormal cells can prevent cervical cancer. The cervical screening guidelines recommend a repeat smear after six months, with colposcopy (where a magnifying device is used to look at the cervix) if the mildly abnormal smear persists, and that “colposcopy for all’’ would involve excessive and wasteful intervention and cause unnecessary anxiety for many women. The aim of this study is to determine whether enabling a woman to choose between a management policy of repeat smears or colposcopy produces a better outcome.

Who can participate?
Women aged 20 to 60 with mildly abnormal cervical smear test results

What does the study involve?
Women are randomly allocated to either the choice group or the no-choice group. Women allocated to the no-choice group had a repeat smear at 6 months. If the smear was normal, a further repeat smear was performed at 12 months and if again normal, the women returned to routine screening. If the smear at six months is abnormal, colposcopy is undertaken. Treatment consists of diathermy loop excision, which involves using a thin heated wire loop to remove the area of the cervix where the abnormal cells are. Patients are followed up six months later by means of smear and colposcopy. If the 12-month smear is abnormal following a normal smear at 6 months, then those women are referred for colposcopy and treatment. Women allocated to the choice group choose between colposcopy and a repeat smear at 6 months, after an opportunity to discuss the two options. Those who choose repeat smears are managed exactly as described above for the no-choice group. Women who select colposcopy are managed according to the colposcopy procedure described above.

What are the possible benefits and risks of participating?
There is no immediate direct benefit to those taking part. As it is necessary for those women with an abnormal smear to be referred to the colposcopy clinic, it could be argued that this visit could make them unnecessarily anxious and more so than if they were recalled by the GP.

Where is the study run from?
St Mary’s Hospital by the University of Manchester (UK)

When is the study starting and how long is it expected to run for?
January to December 2002

Who is funding the study?
National Health Service Research and Development Cancer Programme (UK)

Who is the main contact?
Prof. Henry Kitchener
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Henry Kitchener

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# Additional identifiers

### Protocol serial number
NCP2/R207

# Study information

### Scientific Title
A randomised controlled trial of cytological surveillance versus patient choice between surveillance and colposcopy in managing mildly abnormal cervical smears

### Study objectives
Not provided at time of registration

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Not provided at time of registration

**Study design**
Randomised controlled trial

**Primary study design**
Interventional

**Study type(s)**
Screening

**Health condition(s) or problem(s) studied**
Cancer (neoplasms): Cervix

**Interventions**
1. Normal procedure of repeat smear in 6 months. If normal, a further repeat smear at 12 months. If smear at 6 months was abnormal, colposcopy was undertaken.
2. Patient choice given between colposcopy and 6-months repeat smear. Women who chose colposcopy were managed as for normal procedure arm.

**Intervention Type**
Other

**Phase**
Not Specified

**Primary outcome(s)**
Not provided at time of registration

**Key secondary outcome(s))**
Not provided at time of registration

**Completion date**
31/12/2002

# Eligibility

**Key inclusion criteria**
Women with mildly abnormal cervical smears

**Participant type(s)**
Patient

**Healthy volunteers allowed**
No

**Age group**
Adult

**Sex**
Female

**Key exclusion criteria**
Pregnancy or abnormal vaginal bleeding.

**Date of first enrolment**
01/01/2002

**Date of final enrolment**
31/12/2002

## Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**University of Manchester**
Manchester
United Kingdom
M13 0JH

## Sponsor information

**Organisation**
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

## Funder(s)

**Funder type**
Government

**Funder Name**
NHS Cancer National Research and Development Programme

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2004 | | Yes | No |