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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

Completion date
31/12/2002

Eligibility

Key inclusion criteria
Women with mildly abnormal cervical smears

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
476

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Cancer National Research and Development Programme

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	01/01/2004		Yes	No