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A comparison of automated technology and manual cervical screening

Submission date 11/01/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/01/2005	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-test-a-new-way-of-looking-at-cervical-smear-tests

Study website
http://www.cancerhelp.org.uk/trials/trials/trial.asp?trialno=11269

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 03/04/02

Study information

Scientific Title
A comparison of automated technology and manual cervical screening: a randomised controlled trial

Acronym
MAVARIC

Study objectives
Cervical screening by cytology (smear tests) has proven an effective means of reducing death rate from cervical cancer. Conventional smears (Pap tests) have probably achieved as much as they can in the UK. Some gains will be achieved by the introduction of a new type of sample, obtained by putting the sample into fluid rather than smeared on a slide. These include a reduction in inadequate smears and more rapid reading, both of which will achieve greater efficiency and convenience to women. Pressures on cytoscreeners will lessen.

The use of automated technology may further these benefits by making identification of the abnormal cells easier. Instead of scanning an entire slide the cytoscreeners will be directed to 15-22 locations on a slide by the computerised software. In addition, one of the machines (Focal Point) can sort the abnormal slides into quintiles. In addition, 20-25% are classified as 'no further review' meaning that manual reading is not required.

In order to assess these potential benefits, tight and unbiased comparisons with manual (current) reading are required. This will ensure that women can expect the most accurate and reliable screeing service, which is as cost effective as possible. To be convincing, this type of study needs to be embedded in the NHS Cervical Screening Programme.

Finally human papillomavirus testing is undergoing evaluation internationally as a means of increasing sensitivity of screening (including a Health Technology Assessment Programme funded trial in Manchester). We will use HPV testing to indicate which women with the least abnormal grades of cytology require colposcopy.

Trial details are also available at: http://www.hta.ac.uk/1462
Protocol can be found at: http://www.hta.ac.uk/protocols/200300040002.pdf

Please note that the scientific title was added to this trial record as of 03/02/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Manchester Local Research Ethics Committee, approved on 08/12/2004 (ref: 04/Q1407/318)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Cervical Neoplasia

Interventions
Comparison of the results of manually read cervical cytology slides with those using automated technology

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Added as of 03/02/2009:
The relative sensitivity of screening by automated or manually read cytology to detect CIN3 /invasive cancer (CIN3+) and CIN2, 3 and invasive cancer (CIN2+).

Secondary outcome measures
Added as of 03/02/2009:
Clinical outcomes:
1. The detection rates of CIN2+ and ICN3+ in each arm
2. The detection rates (positive predictive values) for each category of cytology including the threshold of borderline or greater and mild dyskaryosis or greater
3. Relative specificity rates of screening by automated and manual reading
4. All of the above comparing Focal Point™ and Imager™
5. The reliability of no further review in Focal Point™ in terms of negative predictive value using negative manual reading in the paired reading and the reference standard
6. To assess inadequate rates with both technologies

Economics and organisational outcomes:
7. Comparative throughput and reporting times (for each stage of screening)

8. Detailed cost estimate of the total cost of processing smear at the laboratory and total cost per smear including consideration of inadequate rates and using no further review at different cut off-levels
9. Estimate of the comparative cost effectiveness of automated versus manually read cytology using trial data and modelled lifetime costs and effects
10. Assessment of cytoscreeners' experience and satisfaction with automated systems and the organisational changes that automation would require in implementation

Overall study start date
01/08/2005

Completion date
31/10/2009

Eligibility

Key inclusion criteria
100,000 women undergoing primary cervical screening

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100,000 women

Total final enrolment
73266

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2005

Date of final enrolment
31/10/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Obstetrics and Gynaecology
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Sponsor information

Organisation
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Oxford Road
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Sponsor type
Government

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/01/2011		Yes	No
Results article	results	01/01/2011		Yes	No
Plain English results			26/10/2022	No	Yes