

A comparison of automated technology and manual cervical screening

Submission date 11/01/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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 screening 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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Screening

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(s)

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+).

Key secondary outcome(s)

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

Completion date

31/10/2009

Eligibility

Key inclusion criteria

100,000 women undergoing primary cervical screening

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre

Academic Unit of Obstetrics and Gynaecology

Manchester

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Sponsor information**Organisation**

University of Manchester (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary**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
Study website	Study website	11/11/2025	11/11/2025	No	Yes