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# A comparison of automated technology and manual cervical screening

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

## Contact information

**Type(s)**
Scientific

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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 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

## 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 |