

# A comparison of automated technology and manual cervical screening

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

## Study website

<http://www.cancerhelp.org.uk/trials/trials/trial.asp?trialno=11269>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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 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)

**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**  
Manchester  
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## **Sponsor information**

**Organisation**  
University of Manchester (UK)

**Sponsor details**  
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Manchester  
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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?
<a href="#">Results article</a>	results	01/01/2011		Yes	No
<a href="#">Results article</a>	results	01/01/2011		Yes	No
<a href="#">Plain English results</a>			26/10/2022	No	Yes