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A randomised trial of human papillomavirus (HPV) testing in primary cervical screening

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2021	Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/does-an-hpv-test-as-well-as-a-cervical-smear-test-improve-screening-for-cervical-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 98/04/99; HTA 98/04/64

Study information

Scientific Title

A randomised trial of human papillomavirus (HPV) testing in primary cervical screening

Acronym
ARTISTIC

Study objectives
1. To study a randomised population of women undergoing cytological screening in whom an HPV test result is revealed with a smaller cohort in whom the result is concealed.
2. To study the psychological and psychosexual differences between corresponding cytological groups in the two study arms.
3. To study the economic benefits or otherwise of HPV testing.
4. To study the predictive ability of HPV testing positive or negative in the presence of normal cytology in terms of future risk, and screening intervals.
5. To see if HPV testing achieves a more efficient protocol following "inadequate" smears and low grade smears.
6. To evaluate the relevance of viral persistence and load in predicting risk.
7. To evaluate sensitivity, specificity and negative predictive value of HPV testing.
8. To compare the results of different HPV testing methods in terms of objective 7 and also to examine interlaboratory variation.

More details can be found at: http://www.hta.ac.uk/1162
Protocol can be found at: http://www.ncchta.org/protocols/199800040064.pdf

Updated 14/01/2008: the anticipated start and end dates of this trial were updated from 01/04/2000 and 31/03/2006 to 01/06/2001 and 30/11/2009, respectively.

Updated 30/09/2013: the NIHR has awarded funding to extend the follow-up of this trial until 2015. This will be done by linkage with national screening and cancer registration records without recontacting patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Multi-centre Research Ethics Committee, approved on 18/08/2000 (ref: MREC 00/8/30)

Study design
Pragmatic randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Cervical cancer

Interventions

Women who are attending for cervical screening, all of whom will have a smear and an HPV test, will be individually randomised in a ratio of 3:1 to a study arm (HPV test revealed) and a control arm (HPV test concealed). The control arm will be managed by routine clinical practice as per national guidelines with a rescreen and HPV test at 3 years.

1. High grade smears (HPV +ve or -ve) - routine management (colposcopy)
2. Low grade smears (HPV +ve) - routine management (colposcopy)
3. Low grade smears (HPV -ve) - repeat smear at 6/12. If abnormal, colposcopy
4. Normal smears (HPV +ve) - repeat HPV test at 12/12. If persistent HPV +ve, patient choice between colposcopy and surveillance
5. Normal smears (HPV -ve) - rescreen at 36/12. Colposcope 500 volunteers to address true sensitivity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Reduction of high and low grade smears in the HPV revealed arm, at the next screening round
2. The difference in psychological and psychosexual outcomes in the HPV revealed arm as a consequence of knowledge of the HPV test result
3. Cost: the number of women experiencing the cost generating events (cytology, HPV test, colposcopy, biopsy and treatment and ad hoc primary care consultations) will be identified and the associated unit costs will be estimated and attached to these events to determine total costs in each arm. Cost effectiveness will be presented as an incremental cost per additional high grade smear detected, and as an incremental cost per life year gained and per quality adjusted life year gained (estimated by extrapolating from the trial endpoint using modelling techniques).

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/01/2015

Eligibility

Key inclusion criteria
Women aged 20-64 weighted by age bands to achieve a spread of HPV positives across the age range.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
Female

Total final enrolment
24510

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2001

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Academic Unit of Obstetrics & Gynaecology Reproductive Healthcare
Manchester
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Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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	main results	01/07/2009		Yes	No
Results article	results on cost effectiveness and psychosocial effects	01/11/2009		Yes	No
Results article	extended follow-up results	01/04/2011		Yes	No
Results article	extended follow-up results	01/04/2014		Yes	No
Protocol article	protocol	01/02/2010		Yes	No
Plain English results		08/09/2009	29/10/2021	No	Yes