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Alternative technologies in cervical cancer screening

Submission date	Recruitment status	[_] Prospectively registered
15/08/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/04/2016	Cancer	

Plain English summary of protocol

Background and study aims
Cervical cancer is a type of cancer that develops in a woman's cervix (the entrance to the womb from the vagina). It is the second most common cancer in women, and develops as a rare consequence of Human PapillomaVirus (HPV) infection. Cervical screening involves collecting cells from the surface of the cervix in order to detect and remove any abnormal cells. The aim of this study is to evaluate the effectiveness of alternative screening techniques for cervical cancer (screening that uses an automated method to analyse the cells, and screening that tests for HPV DNA) compared with conventional screening.

Who can participate?
Women invited to the routine cervical cancer screening programme

What does the study involve?
Participants are randomly allocated to undergo automation-assisted screening, HPV-DNA based screening, or conventional screening.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Finnish Cancer Registry (Finland)

When is the study starting and how long is it expected to run for?
January 1999 to December 2020

Who is funding the study?
Finnish Cancer Registry (Finland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Alternative technologies in cervical cancer screening

Study objectives
Cervical cancer, the second most common cancer in women worldwide, develops as a rare consequent of common Human PapillomaVirus (HPV) infection. Precancerous lesions precede development of invasive cancer.

Hypothesis:
To evaluate effectiveness of alternative screening techniques using register-based cervical cancer incidence and mortality as the gold standard. Along with sensitivity, also specificity and corresponding test and treatment rates will be compared between the screening modalities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
There is a continuous linkage between invitation, screening and cancer registry files, based on the national legal framework for organised screening (Act and By-law on Public Health, 1992) and for data collection within health care in Finland (Act and By-law on National Personal Records Kept under the Health Care System, 1989). Study protocols and information procedures

for each individual technique currently under evaluation have been accepted by Ethical Committee of the National Research and Development Centre for Welfare and Health (STAKES, 4151/54/98), by the Ethical Committee of the Obstetrics and Gynaecology in Hospital District of Helsinki and Uusimaa (221/E8/02), by the National Authority for Medicolegal Affairs (3950/32 /300/02).

Study design
Prospective randomised evaluation trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 cancer

Interventions
Alternative screening techniques (automation-assisted cytological screening, and HPV-DeoxyriboNucleic Acid [DNA] based screening) are compared to conventional cytological screening.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Subsequent cervical cancer incidence among women invited

Secondary outcome measures
1. Mortality from cervical cancers.
2. Detection and incidence of precancerous lesions

Overall study start date
01/01/1999

Completion date

31/12/2020

Eligibility

Key inclusion criteria
Women invited to routine cervical cancer screening programme within municipalities contracted

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
900,000

Key exclusion criteria
N/A

Date of first enrolment
01/01/1999

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Finland

Study participating centre
Liisankatu 21 B
Helsinki
Finland
FI-00170

Sponsor information

Organisation
Finnish Cancer Registry (Finland)

Sponsor details

Liisankatu 21 B
Helsinki
Finland
FI-00170

Sponsor type
Research organisation

Website
http://www.cancerregistry.fi

ROR
https://ror.org/00j15sg62

Funder(s)

Funder type
Government

Funder Name
Finnish Cancer Registry (Finland)

Funder Name
European Commission (Belgium) - Europe Against Cancer action programme, through European Cervical Cancer Screening Network (ref: SPC.2002475)

Funder Name
Finnish Cancer Organisations (Finland) (grant refs: 14.11.2003, 11.11.2004)

Funder Name
Academy of Finland (Finland) (ref: 73399, date: 25.10.2000)

Alternative Name(s)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	20/01/2003		Yes	No
Results article	results	01/08/2004		Yes	No
Other publications	interim evaluation of the automation-assisted screening	10/06/2005		Yes	No
Results article	results on the cross-sectional relative validity parameters for routine hrHPV screening	17/10/2005		Yes	No
Results article	results	15/02/2006		Yes	No
Protocol article	protocol	16/10/2006		Yes	No
Results article	results	02/12/2009		Yes	No
Results article	results	27/04/2010		Yes	No
Results article	results	29/11/2012		Yes	No
Results article	results	01/05/2013		Yes	No