

Alternative technologies in cervical cancer screening

Submission date 15/08/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/04/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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Additional identifiers

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

Study type(s)

Screening

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(s)

Subsequent cervical cancer incidence among women invited

Key secondary outcome(s)

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

Completion date

31/12/2020

Eligibility**Key inclusion criteria**

Women invited to routine cervical cancer screening programme within municipalities contracted

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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)

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)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Finland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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
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
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
Protocol article	protocol	16/10/2006		Yes	No
Other publications	interim evaluation of the automation-assisted screening	10/06/2005		Yes	No