Self-sampling vs. reminder letter: effects on cervical cancer screening attendance and coverage

Submission date Recruitment status Prospectively registered 13/02/2010 No longer recruiting [] Protocol Statistical analysis plan Overall study status Registration date 06/04/2010 Completed [X] Results [] Individual participant data Last Edited Condition category 10/04/2012 Cancer

Plain English summary of protocol

Not provided at time of registration

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 N/A

Study information

Scientific Title

Self-sampling vs. reminder letter: A randomised controlled trial to investigate the effects on cervical cancer screening attendance and coverage

Study objectives

Self-sampling is more efficient than a written reminder letter in improving cervical cancer screening attendance and coverage among current non-attendees

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved by the Ethical Committee in Hospital District of Helsinki and Uusimaa in March 2008 (ref: 430/E9/07 HUS). It was also approved by the City of Espoo.

Study design

Randomised open label controlled parallel group 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 contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Cervical cancer screening

Interventions

All non-participants after the primary cervical cancer screening invitation in the city of Espoo in years 2008 and 2009 received either a high-risk (hr) Human Papillomavirus (HPV) self-sampling test or a written reminder letter.

Both arms received an information letter on the study, information pamphlet on cervical cancer screening and HPV.

Participants in the self-sampling arm also received an informed consent sheet, Pantarhei Screener® self-sampling device (Panterhei Devices, Netherlands) and user instruction sheet on the use of the self-sampling test. Women to be screened were asked to use the sample within 2 weeks of its arrival and mail the sample within 24 hours of sample taking. Results of the screening test were promised within 2 months of the return.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Increase in attendance and coverage of cervical cancer screening

Secondary outcome measures

- 1. Prevalence of hrPV-infections higher among those women that do not participate cervical cancer screening after the primary invitation.
- 2. Feasibility, usability and acceptance of self-testing among women

Overall study start date

01/11/2008

Completion date

31/05/2010

Eligibility

Key inclusion criteria

Women, ages 30-65, living in the city of Espoo who received an invitation to cervical cancer screening but did not take part.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

approximately 9000

Key exclusion criteria

Address information for non-participants was updated from the Population Register Centre before the interventions were sent and women who had no address information available, were dead or living outside Espoo were excluded.

Date of first enrolment

01/11/2008

Date of final enrolment

31/05/2010

Locations

Countries of recruitment

Finland

Study participating centre Pieni Roobertinkatu 9

Helsinki Finland 00130

Sponsor information

Organisation

Finnish Cancer Organisations (Finland)

Sponsor details

Pieni Roobertinkatu 9 Helsinki Finland 00130

Sponsor type

Research organisation

Website

http://www.cancer.fi

ROR

https://ror.org/05pgg4z49

Funder(s)

Funder type

Research organisation

Funder Name

Finnish Cancer Organisations (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	01/09/2011		Yes	No