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Interventions to increase participation in the cervical cancer screening program for non-attendees in Sweden

Submission date
17/01/2020

Recruitment status
No longer recruiting

Registration date
23/01/2020

Overall study status
Completed

Last Edited
05/07/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cervical cancer is a highly preventable disease. To not attend an organized cervical cancer screening program increases the risk for cervical dysplasia and cervical cancer. The aim is to investigate the participation rate in three different intervention groups for non- attendees in the Swedish national program for cervical screening.

Who can participate?
Women who have not participated in the cervical cancer screening programme during the last six years if aged 30-49 and the last eight years if aged 50-64.

What does the study involve?
Women participating in the study are offered different methods for cervical cancer screening; a visit to a midwife for a Pap smear or an HPV self-test.

What are the possible benefits and risks of participating?
If women participate and dysplasia is detected it can be treated before it develops into cervical cancer.
We can not identify any risk of great importance.

Where is the study run from?
Faculty of Medicine and Health Sciences, Linköping University, Sweden.

When is the study starting and how long is it expected to run for?
April 2016 to December 2017.

Who is funding the study?
ALF Grants Region Östergötland, Sweden.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Participation in interventions and recommended follow-up for non-attendees in cervical cancer screening- taking the women's own preferred test method into account - a Swedish randomised controlled trial

Study objectives

The participation rate will increase if the non-attendees can choose between different test methods presented by a midwife in a telephone call (an HPV self-test or Pap Smear in the clinic) or if they receive an HPV self-test directly by post for sampling rather than yearly invitations (routine procedure)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2016, Regional Ethical Review Board in Linköping, Sweden (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: Dnr 2015/480-31

Study design
Single centre Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact detalis to request participant information sheet

Health condition(s) or problem(s) studied
Cervical cancer and cervix dysplasia

Interventions
Non-attendees are defined as women who had not participated in the cervical cancer screening programme during the last six years if aged 30 - 49, and the last eight years if aged 50 - 64. This strategy was in accordance with the Swedish age-differentiated screening intervals at that time. The population was defined as non-attendees living in the region of Östergötland, Sweden on March 8th 2016. Data are extracted from the Swedish national cervical cancer screening registry (NKCx) which has almost 100% coverage of invitations. The results of Pap smears and biopsies and variables can be extracted from the unique national social security number for each individual. The results from the HPV self-tests are extracted from a local registry in the clinic. Data concerning follow-up results are obtained until the 31st of December 2017 when the study period will end. The non-attendees' addresses are obtained from the Swedish Population Register (SPR). The trial was not registered before the enrolment of participants started because it was not recommended by the Ethical board.

The non-attendees are randomly, 1:1:1, assigned to one of three different groups: telephone, HPV self-test, or control with no intervention except for the yearly invitations (routine

procedure). The study groups are computer randomised and adjusted for area code and age by a statistician uninvolved in the study. All three groups received the yearly invitations. The first analysed sample, Pap smear or HPV test, in all groups is referred to as the index sample. We will consider that the different interventions had an effect if an HPV self-test is ever returned during the study period or a Pap smear is analysed within six months from the date a study invitation letter is sent. Non-attendees randomised to the telephone group are offered a choice of different sampling options. Invitation letters are posted between April 1st 2016 and 31st May 2017 (telephone) and September 30th 2017 (HPV self-test).

Intervention Type
Behavioural

Primary outcome measure
Participation rate measured using patient records at six months after invitations were sent

Secondary outcome measures
1. Choice of intervention measured using patient records at the end of the study
2. Cytological diagnoses found in the index Pap smear at the time of analysis

Overall study start date
08/03/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Non- attendees (defined as women who had not participated in the cervical cancer screening programme during the last six years if aged 30-49 and the last eight years if aged 50-64)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
10,614

Total final enrolment
10614

Key exclusion criteria
All women 30-64 years old that had participated after the last invitation as recommended in the cervical cancer screening program

Date of first enrolment
01/04/2016

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
Department of Obstetrics and Gynaecology
Division of Children's and Women's Health
Faculty of Medicine and Health Sciences
Linköping
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58185

Sponsor information

Organisation
Linköping University Hospital

Sponsor details
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Sponsor type
Research organisation

Website
http://www.regionostergotland.se/

ROR
https://ror.org/05h1aye87

Funder(s)

Funder type
Government

Funder Name
ALF Grants Region Östergötland

Results and Publications

Publication and dissemination plan
Publication in scientific paper during 2020. Presentation in congress and for staff.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/07/2020	05/07/2020	Yes	No