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The effect of a self-sampling device for human papillomavirus (HPV) test on the women's participation to cervical cancer screening in Italy

Submission date 24/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/05/2010	**Overall study status** Completed	
Last Edited 24/02/2011	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

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
The effect of a self-sampling device for human papillomavirus (HPV) test on the women's participation to cervical cancer screening in Italy: a four-arm randomised controlled trial

Study objectives
The use of a self-sampler may remove some of the barriers for women's participation to cervical cancer screening programs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee of ISPO, a Cancer Prevention and Study Centre, approved on the 6th June 2008 (ref: 6)

Study design
Four-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

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

Interventions
Control 1: standard recall letter to perform Pap test at the clinic
Control 2: standard recall letter to perform Pap test at the clinic
Intervention 1: direct mailing of the self sampling device at home
Intervention 2: invitation to contact the centre to receive the self sampling device at home

Total duration of follow-up for all arms: 3 months.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Performing a test (HPV or Pap) within 3 months since the recall letter.

Secondary outcome measures
How many of the women performing a test after the intervention were never-screened or under-screened (last Pap test more than 3 years before)?

Overall study start date
01/02/2009

Completion date
20/11/2009

Eligibility

Key inclusion criteria
All women (aged 35 - 64 years) non-responding to the screening invitation in the previous year and eligible for recall

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
600 women per arm (total 2400)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2009

Date of final enrolment
20/11/2009

Locations

Countries of recruitment
Italy

Study participating centre
Laziosanità - Agenzia di Sanità Pubblica, Regione Lazio
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Sponsor information

Organisation
Centre for Disease Control and Prevention, Italian Ministry of Health (Italy)

Sponsor details
Viale Giorgio Ribotta, 5
Rome
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Sponsor type
Government

Website
http://www.ministerosalute.it/

ROR
https://ror.org/00789fa95

Funder(s)

Funder type
Government

Funder Name
Centre for Disease Control and Prevention, Italian Ministry of Health (Italy)

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	18/01/2011		Yes	No