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New Technologies for Cervical Cancer screening

Submission date 29/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/06/2005	**Overall study status** Completed	
Last Edited 03/04/2013	**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

Acronym
NTCC

Study objectives
Women who test negative in the experimental arm have a lower risk than women who test negative in the conventional arm of having a high-grade pre-invasive lesion detected in the three years following screening, therefore allowing longer screening intervals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The NTCC study was approved by the local research ethics committees of the participating centres. Ethical approval was obtained by the Dutch Ministry of Health, Welfare, and Sport for the NETHCON trial

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

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

Interventions
Women in conventional arm have conventional cytology and are referred for colposcopy according to the standard regular protocols.

Experimental arm follows two phases:
In phase 1, women have both liquid based cytology and human papillomavirus (HPV) testing (by Hybrid Capture 2) for high risk types. Women aged 35 years or more are referred for colposcopy if either HPV is positive or cytology is atypical cells of undetermined significance (ASCUS) or more severe. Women of age less than 35 are directly referred for colposcopy if cytology is ASCUS or more severe. If HPV is positive but cytology is less than ASCUS women are invited for repeating both tests after one year and referred for cytology if either is positive.

In phase 2, women in the experimental arm are tested only for HPV and are referred for colposocpy if it is positive, independently of age.

Women in both arms are be recalled for new screening by conventional cytology after three years. The detection of CIN2+ after recruitment and up to re-screening included will be compared.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure is the detection rate (DR) of histologically confirmed cervical intraepithelial neoplasia grade 2 or more severe (CIN2+). In order to test the study hypothesis we will consider DR of CIN2+ after recruitment and up to including re-screening among women who tested negative at recruitment. The DR of CIN2+ at recruitment will be studied in order to investigate the cross sectional sensitivity of new technologies compared to conventional cytology (hypothesis: higher DR in experimental arm). The overall DR at recruitment and up to including re-screening in the two arms will be compared in order to study the relative over-diagnosis of regressive lesions.

Secondary outcome measures
Main secondary outcome measures are the referral rate to colposcopy and the positive predictive value for CIN2+ in the two study arms.

Overall study start date
01/02/2002

Completion date
31/12/2004

Eligibility

Key inclusion criteria
Women 25 to 60 years old coming for a new screening episode in nine organised cervical screening programmes

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
94,000

Key exclusion criteria
1. Virgin
2. Pregnant
3. Hysterectomised
4. Treated for cervical cancer or intraepithelial lesions in last five years

Date of first enrolment
01/02/2002

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Italy

Study participating centre
Via San Francesco da Paola 31
Torino
Italy
10123

Sponsor information

Organisation
CPO Piemonte (Italy)

Sponsor details
Via San Francesco da Paola 31
Torino
Italy
10123

Sponsor type
Government

ROR
https://ror.org/05v0e5774

Funder(s)

Funder type

Government

Funder Name
Italian Ministry of Health (Italy) - progetto speciale "Valutazione di nuove tecnologie per lo screening del cervicocarcinoma" and progetto speciale "Nuove tecnologie per lo screening del cervicocarcinoma. Follow-up"

Funder Name
European Union (Belgium) - Europe Against Cancer contracts SI2.327046 and SPC.2002475

Funder Name
Regional Administrations of the Italian Regions involved (Piemonte, Veneto, Emilia-Romagna, Toscana, Lazio and Provncia Autonoma di Trento)

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	01/07/2006		Yes	No
Results article	results	07/07/2007		Yes	No
Results article	results of blind revision of historic lesions	01/01/2008		Yes	No
Results article	results	01/03/2010		Yes	No
Results article	age-specific patterns of unsatisfactory results	01/08/2010		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results of nested substudy	01/02/2013		Yes	No