Diagnostic accuracy of the ThinPrep liquid based versus conventional cytology.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23685

Source
NTR

Brief title
Nethon

Health condition

1. Cervical cancer screening;

2. liquid based cytology;

3. ThinPrep;

4. conventional cytology.

Sponsors and support

Primary sponsor: Radboud Univerity Nijmegen
Source(s) of monetary or material Support: European commission, through the European Network for Cervical Cancer Screening (contract:), the
European Cancer Network and the Dutch Ministery of Health, through the National Institute for Public Health and Environment.

Intervention

Outcome measures

Primary outcome

1. Cost effectiveness in terms of incremental cost per additional abnormal case detected;

2. Costs per invasive cancer prevented and life years gained.

Secondary outcome

Diagnostic accuracy in terms of detection rate ratios of cervical intraepithelial neoplasia and cancer, gain in sensitivity and positive predictive value.

Study description

Background summary

In this trial, cost-effectiveness and accuracy of the liquid-based ThinPrep cytology is compared with conventional cytology. The two-centre, cluster randomized controlled trial is performed within the national cervical screening program and includes 90.000 participants. The results of this trial will be helpful to determine whether implementation in the national cervical screeningprogram will be useful.

Study objective

There are clues that the ThinPrep method has a higher detection of cervical epithelial abnormalities. A cost-effectiveness study is needed to determine whether implementation in the Dutch national cervical screening program is useful.

Study design

N/A

Intervention

Comparing performance of ThinPrep with conventional cytology.

Contacts

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Eligibility criteria

Inclusion criteria

Women, participating in the national cervical screening program, recruited from family practices who were randomised to experimental arm (ThinPrep) or control arm (conventional cytology).

Exclusion criteria

N/A

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2003
Enrollment:	90000
Type:	Actual

Ethics review

Positive opinion

Date:	31-07-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1003
NTR-old	NTR1032
Other	: EU/CVZ nummer
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Cytological detection of cervical abnormalities with the ThinPrep liquid based versus conventional cytology: population based randomised controlled trial.