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Post treatment cervical intraepithelial neoplasia: randomised controlled trial using high-risk human papilloma virus testing for prediction of recurrent or residual disease

Submission date
06/03/2007

Recruitment status
No longer recruiting

Registration date
06/03/2007

Overall study status
Completed

Last Edited
24/12/2008

Condition category
Cancer

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

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
NTR908

Study information

Scientific Title

Study objectives
According to the current national guidelines, as formulated by the Dutch Society of Cervical Pathology and Colposcopy in 1995, the follow-up in women treated for high grade cervical intraepithelial neoplasia (CIN) lesions consists of cervical cytological monitoring at 6, 12 and 24 months. Colposcopic examination will be performed in case of abnormal cervical cytology. One of the drawbacks of cervical cytological follow-up after treatment is a high number of false-positive findings. Approximately 20% of the women present an abnormal cervical cytology. However in only half of them an underlying residual or recurrent CIN will be found, resulting in unnecessary diagnostic procedures to determine the actual residual or recurrent CIN disease.

From several studies we know that a persistent infection with high-risk human papillomavirus (HPV) is necessary for the development, maintenance and progression of primary CIN lesions. It is assumed that effective treatment for CIN lesions results in the eradication of the high-risk HPV infection present before treatment. However in residual or recurrent CIN disease, is high-risk HPV still present? The use of the high-risk HPV-test during follow-up, as an adjunct to cytological follow-up, will lead to a better selection of those women at risk for residual or recurrent CIN after initial treatment for high-grade CIN lesions.

This selection results in diagnostic procedures only in patients with actual risk for developing recurrent or residual CIN lesions. Unnecessary diagnostic procedures in patients without residual or recurrent CIN can be prevented. Consequently, this policy leads to can lead to important reduction in health costs. Moreover, a better quality-of-life for the woman can be obtained.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethical Research Commission Erasmus University Medical Centre Rotterdam (Medische Ethishe Toetsings Commissie Erasmus MC) on the 6th February 2002 (ref: MEC 197.749/2000/266).

Study design
Randomised, non-controlled, parallel group, multicentre clinical trial

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Post treatment CIN, cytology, high-risk HPV testing

Interventions
During follow-up after treatment for high-grade CIN (6, 12 and 24 months) cytology and high-risk HPV testing will be performed. Colposcopic examinations will be performed in case of abnormal cervical cytology (current policy group A) or both abnormal cervical cytology and a positive HPV test (group B). At the end of follow-up all participants, irrespective of the test results, will undergo colposcopic examination for end-histology to exclude residual or recurrent CIN lesions and to establish specificity and sensitivity of both follow-up policies.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The reduction in the number of false-positives achieved by combined testing, through increasing the specificity of testing with unaltered sensitivity, resulting in fewer diagnostic procedures.

Secondary outcome measures
1. A decrease in unnecessary examinations and treatment
2. Possible influence of high-risk HPV genotyping and effects on health-costs

Overall study start date
01/07/2002

Completion date
01/09/2004

Eligibility

Key inclusion criteria
Women indicated to be treated for high-grade CIN lesions.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
204

Key exclusion criteria
1. Previous treatment for high-grade CIN
2. An immune compromised state
3. Previous or current cancer

Date of first enrolment
01/07/2002

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus University Medical Centre Rotterdam
Rotterdam
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3000 CA

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands)

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	15/02/2009		Yes	No