

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	☐ Prospectively registered
Registration date 06/03/2007	Overall study status Completed	☐ Protocol
Last Edited 24/12/2008	Condition category Cancer	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof T H J M Helmerhorst

Contact details

Erasmus University Medical Centre Rotterdam
Department of Obstetrics and Gynaecology
P.O. Box 2040
Rotterdam
Netherlands
3000 CA
+31 (0)10 463 3381
t.helmerhorst@erasmusmc.nl

Additional identifiers

Protocol serial number

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 Ethische Toetsings Commissie Erasmus MC) on the 6th February 2002 (ref: MEC 197.749/2000/266).

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

01/09/2004

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

Results and Publications

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