Fluorescence and reflectance spectroscopic imaging scan for detection of cervical neoplasia

Published: 28-08-2014
Last updated: 21-04-2024

To determine sensitivity, specificity, positive predictive value and negative predictive value of the spectroscopic cervical imaging device in detection of high grade cervical intraepithelial neoplasia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cervix disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON41942

Source
ToetsingOnline

Brief title
Multimodal hyperspectroscopy for detection of cervical neoplasia

Condition

- Cervix disorders (excl infections and inflammations)

Synonym
Cervical intraepithelial neoplasia, precancerous cervical cells

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,voorgaand HPV-gerelateerd onderzoek

Intervention

Keyword: Cervical Intraepithelial Neoplasia, Colposcopy, Fluorescence and reflectance spectroscopy, pap-smear

Outcome measures

Primary outcome

The main study parameters are sensitivity, specificity, positive predictive value and negative predictive value of the multimodal hyperspectroscopy cervical scan to detect high grade cervical intraepithelial neoplasia. The result of the cervical scan will be compared to the result of the hrHPV test.

Secondary outcome

Secundary study parameters are: ease of use of the cervical scan and adverse events of the scan for the patient. Duration of the scan and additional time needed for the appointment because of the scan will also be evaluated.

Study description

Background summary

Invasive cervical cancer is preceded by a state of cervical intraepithelial neoplasia (CIN). Cervical cancer screening is known to decrease cancer incidence by early detection and treatment of high grade CIN lesions. Limited sensitivity and specificity of different screening- and triage-options, result in missed lesions or overtreatment. Previous studies have shown that a cervical scan based on fluorescence and reflectance spectroscopy is a potential method for triaging women at risk for moderate and high grade dysplasia. Fluorescence and reflectance spectroscopy has been successfully evaluated in a small number of clinical trials for detecting neoplasia of the cervix. Before it can be used as an integrated triage test, validation of previously published results is essential.

Study objective

To determine sensitivity, specificity, positive predictive value and negative

predictive value of the spectroscopic cervical imaging device in detection of high grade cervical intraepithelial neoplasia.

Study design

Prospective multi-centre cohort study

Intervention

Patients will undergo a, one minute, spectroscopic cervical vaginal scan, performed by a healthcare worker in the outpatient clinic. Also an additional hrHPV test with genotyping will be performed on a cervical smear. In most cases a cervical smear will be taken for standard examination. When this is not the case, an additional smear will be taken for the hrHPV test.

Study burden and risks

Patients that undergo regular colposcopic evaluation or a control pap-smear will undergo an additional multimodal spectroscopy cervical scan. This scan had previously been described to be without serious adverse events and well accepted by women. No tissue samples are taken during the scan, no additional hospital visits or questionnaires are needed. When no cervical smear is taken during regular diagnostics, an additional smear is taken for the study hrHPV test. The burden/risk of this additional smear is small.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >=18 years
Requiring colposcopic evaluation or requiring control pap-smear after previous treatment or with a watchful waiting policy

Exclusion criteria

Currenty pregnant or pregnancy in the last 3 months
Currently undergoing treatment for cervical cancer
Current menstruation
Previous pelvic radiotherapy
High-grade cervical smear

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2014

Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	cervical multimodal spectroscopy scan
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-08-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL49282.091.14

Study results

Date completed:	25-07-2016
Actual enrolment:	152