Biomarker detection in cytololgy samples of women with gynaecological cancer: a multicentric study

Published: 04-07-2016
Last updated: 17-04-2024

To study the value of molecular biomarkers in cytology samples (cervical scrape, vaginal sample and urine) for cancer detection in patients with gynaecologic cancer.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON55675

Source
ToetsingOnline

Brief title
Biomarker detection in cytololgy of women with gynaecological cancer

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
gynaecological cancer, gynaecological malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: financiering uit bestaande onderzoeksprojecten

Intervention

Keyword: biomarkers, cervical cytology, gynaecologic cancer, methylation

Outcome measures

Primary outcome

Biomarker levels (for example methylation levels) in several cytology samples of participants/patients with endometrial or cervical cancer are the primary parameter in this study. The proportion of cytology samples with a positive test result will be measured in cancer cases (participants/patients with endometrial or cervical cancer). Sensitivity and specificity will be calculated. In de pilotstudie, the association between the testresult and teh outcome of the study will be studied (benign of malignant ovarian proces).

Secondary outcome

Biomarker levels in diagnostic tumor material will be measured and related to levels found in cytology samples.

Study description

Background summary

Studies have shown that testing for molecular biomarkers (such as methylation markers and miRNAs) in cytology samples (including cervical scrapes, vaginal samples and urine) can be useful to detect underlying endometrial or cervical disease. Therefore, the new screening programme for cervical cancer (starting early 2017) has the potential to be more effective when, beside (pre) malignant cervical disease, other gynaecologic diseases, like endometrial cancer could be detected as well. Early detection of cancer will lead to better outcome in cancer patients. The pilot study in patients with and ovarian neoplasm is set up to see if is is possible to better predict the nature of the ovarian neoplasm (benign of malignant) which is important for monitoring and type of surgery.

Study objective

To study the value of molecular biomarkers in cytology samples (cervical scrape, vaginal sample and urine) for cancer detection in patients with gynaecologic cancer.

Study design

Prospective multicentre cross-sectional study

Study burden and risks

In this study, health risks associated with procedures to collect the different cytology samples (ie cervical scrape, vaginal sample and urine) can be considered negligible. The physical burden is considered minimal as collection of cytology samples will be without or with minimal discomfort. No pain is expected to be related to the collection of vaginal and urine samples. Women can experience an unpleasant sensation for a few seconds during sampling of the cervical scrape. It should be noted that the cervical scrape will be taken during a regularly planned gynaecologic examination. No extra gynaecologic examination is needed for this study. When the cervical scrape is planned during the operation, there will be no extra discomfort. By combining the high numbers of potential study participants treated at the gynaecology departments of CGOA and availability of tumour tissues at pathology departments with professional collaborations between academic gynaecologists, pathologists, molecular biologists and biostatisticians that have extensive experience on doing clinical and translational research, the basis of a successful setting for this study is consolidated. This study will neither interfere with the regular clinical care, nor with the cancer treatment, nor with the outcome of the cancer.

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

1) presence of endometrial or cervical cancer or, for the pilot study, planned surgery for an ovarian neoplasm
2) (expected) availability of diagnostic material of the tumor (histology tissue in referal or refered hospital)
3) possibility to collect cytology (cervical swab, vaginal sample and/or urine) prior to cancer treatment or surgery.
4) age 18 years or older

Exclusion criteria

1) No primary endometrial or cervical cancer or, for the pilot study, no planned sugery for an ovarian neoplasm
2) No (residual) tumour at time of inclusion
3) No possibility to collect cytology samples prior to cancer treatment
4) Age younger than 18 years

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-10-2016
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO Date:	04-07-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	01-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL56664.029.16