Detecting endometrial and ovarian cancer with the Pap-smear

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22188

Source
Nationaal Trial Register

Brief title
DISCOVER: DIagnostig Smear of the Cervix in OVarian and Endometrial canceR

Health condition

Endometrial cancer
Ovarian cancer
Endometriumcarcinoom
Ovariumcarcinoom
Eierstokkanker
Baarmoederslijmvlieskanker
Pap-smear
Uitstrijkje

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Ruby and Rose Foundation

Intervention

Outcome measures

Primary outcome

Sensitivity and specificity of the Pap-smear in detecting endometrial and ovarian cancer

Secondary outcome

The sensitivity and specificity of the cervicovaginal self-sample and the Pipelle endometrial biopsy in detecting endometrial and ovarian cancer.

The correlation between DNA alterations in the cervicovaginal self-sample, the Pap-smear and the Pipelle endometrial biopsy and clinicopathologic parameters

Study description

Background summary

Rationale: In 2011, 1257 women in The Netherlands were diagnosed with ovarian cancer and 1913 with endometrial cancer, causing respectively 1043 and 484 deaths. Ovarian cancer has few symptoms in an early stage and is usually diagnosed in an advanced stage, leading to a bad prognosis. Endometrial cancer has a better prognosis, but the incidence is still rising. Earlier detection or even screening for these diseases would help improve survival. Recent developments in DNA analysis might be used to diagnose ovarian and endometrial cancer with a Pap-smear.

Objective: To verify the feasibility of using the Pap-smear in diagnosing endometrial and ovarian cancer.

Study design: Prospective multicentre cohort study.

Study population: Endometrial cancer: all patients presenting with preoperative diagnosis of endometrial cancer (via pipelle endometrial biopsy or dilatation and curettage) . Ovarian cancer: all patients scheduled for surgery for suspected ovarian cancer (RMI>200, ascites). Controls: patients undergoing at least a hysterectomy for benign pathology.

Intervention: Patients with ovarian or endometrial cancer will undergo a Pap-smear and pipelle endometrial sampling. Mutation analysis results will be compared to mutation analysis

of the primary tumour as well as a Pap-smear and pipelle endometrial sampling performed in subjects without cancer of the female reproductive tract.

Main study parameters: The main study parameter is the correlation between mutations found in the Pap-smear, cervicovaginal self-sampling and pipelle endometrial sampling and the primary tumour.

Study objective

It is possible to detect altered DNA from endometrial and ovarian cancer cells in the Pap-smear by analysing a set of predetermined genes

Study design

T0: Preoperative collection of the cervicovaginal self-sample, Pap-smear and Pipelle endometrial biopsy

Intervention

Cervicovaginal self-sample, Pap-smear and Pipelle endometrial biopsy

Contacts

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Eligibility criteria

Inclusion criteria

Endometrial cancer: all patients presenting with preoperative diagnosis of endometrial cancer (via pipelle endometrial biopsy or dilatation and curettage).

Ovarian cancer: all patients scheduled for surgery for suspected ovarian cancer (RMI>200, ascites).

Controls: patients undergoing at least a hysterectomy for benign pathology.

Exclusion criteria

Patients who received pelvic radiation in the past and patients with ovarian cancer who do not have a uterus will not be able to participate in this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion
Date: 29-11-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39020
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4031
NTR-old	NTR4299
CCMO	NL45143.091.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39020

Study results

Summary results
N/A