Feasibility of using the Pap-smear as a screening device for the detection of endometrial and ovarian cancer

Published: 29-11-2013
Last updated: 15-05-2024

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

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

Summary

ID

NL-OMON39020

Source
ToetsingOnline

Brief title
Detecting endometrial and ovarian cancer with the Pap-smear

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Cervical smear (Pap-smear), uterine cancer (endometrial cancer)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Stichting Ruby & Rose

Intervention

Keyword: Cervicovaginal self-sampling, Endometrial cancer, Ovarian cancer, Pap-smear

Outcome measures

Primary outcome

The main study parameter is the correlation between mutations found in the

Pap-smear and the pipelle endometrial sampling and the primary tumor.

Secondary outcome

The main study parameter is the correlation between mutations found in the

vaginal swab and the pipelle endometrial sampling and the primary tumor.

To assess the correlation between the results of the mutation analysis and

tumour characteristics (histology, stage).

Study description

Background summary

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. The possible upcoming change from the traditional screening for cervical cancer to HPV testing raises a second question whether DNA isolation is possible from this test as well.

Study objective

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

Study design

Prospective multicentre cohort study.

Study burden and risks

All patients with postmenopausal bleeding are suspected of having endometrial cancer and therefore undergo a Pap-smear and a pipelle endometrial sampling. The vaginal swab is an extra test, but this can be performed during routine gynaecologic examination, which means there will be no extra burden or risk. Patients suspected of having ovarian cancer and patients undergoing a hysterectomy for benign pathology normally do not undergo a Pap-smear, vaginal swab and pipelle endometrial sampling. The Pap-smear and vaginal swab can be done during routine gynaecologic examination and will not be an extra burden or risk. The pipelle endometrial sampling is done preoperative, these patients are sedated and won*t experience extra discomfort and there will be no extra risk. These diagnostic tests are extensively used by gynaecologists and were proven to be safe.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6525GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Endometrial cancer: patient suspected of having endometrial cancer i.e. postmenopausal bleeding
Ovarian cancer: patient highly (99% certainty) suspected of having ovarian cancer. This will be based on RMI>200, CA125/CEA ratio, ascites, peritoneal depositions, omental cake or even laparoscopic evaluation.

Exclusion criteria

Previous pelvic radiotherapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2013
Application type:	First submission
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

ID: 22188
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45143.091.13
OMON	NL-OMON22188