Detecting endometrial and ovarian cancer with the Pap-smear

Gepubliceerd: 29-11-2013 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22188

Bron
Nationaal Trial Register

Verkorte titel
DISCOVER: DIagnostig Smear of the Cervix in OVarian and Endometrial canceR

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: Ruby and Rose Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

VU University Medical Center, Department of Otolaryngology /Head and Neck Surgery, Boelelaan 1117

L. Putten, van der
Boelelaan 1117
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4443690

Wetenschappelijk

VU University Medical Center, Department of Otolaryngology /Head and Neck Surgery, Boelelaan 1117

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Boelelaan 1117
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4443690

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39020
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A