Pilot study of the lavage of the uterine cavity for the diagnosis of serous tubal intraepithelial carcinoma

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Detect exfoliated cells from STICs in lavage fluid from the uterine cavity and proximal fallopian tubes

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

Summary

ID

NL-OMON40714

Source
ToetsingOnline

Brief title
LUSTIC Study

Condition

- Reproductive neoplasms female malignant and unspecified
- Ovarian and fallopian tube disorders

Synonym
precursor lesion of ovarian cancer, serous tubal intraepithelial carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitätsklinik für Frauenheilkunde
Source(s) of monetary or material Support: Medische Universiteit van Wenen

Intervention

Keyword: lavage of the uterine cavity, ovarian cancer, screening, serous tubal intraepithelial carcinoma

Outcome measures

Primary outcome

The correlation between the presence of STICs in the tubes and exfoliated STIC

cells in lavage fluid from the uterine cavity and proximal fallopian tubes.

Secondary outcome

No

Study description

Background summary

High grade serous ovarian cancer (HGSC) is the leading cause of death from gynecologic malignancy in western civilized countries. It is usually detected at an advanced stage and five-year survival rates are in the range of 10 to 30 %. Definitive diagnosis of HGSC mostly relies on surgical confirmation and there is a need for an effective test for early detection. The specificity of current diagnostic tools is low and ineffective at detecting HGSC early enough to improve clinical outcomes. Recent findings have shown that it is possible to detect ovarian cancer cells in lavage fluid from the uterus and proximal tubes very effectively.
There is increasing evidence that a large proportion of not only familial HGSC develop primarily in the lining of the fallopian tube. If cells from these serous tubal intraepithelial carcinomas can be detected in lavage fluid from the uterus and proximal fallopian tubes, it would be possible to detect ovarian cancer in a pre-malignant stage, making it much easier to treat and increase the survival significantly.

Study objective

Detect exfoliated cells from STICs in lavage fluid from the uterine cavity and proximal fallopian tubes

Study design

Prospective multicentre cohort study

Study burden and risks

The risk that STIC cells will get washed in to the peritoneal cavity during the lavage and form metastases in the peritoneal cavity is remote. This risk is balanced against the benefit of developing a screening test or early detection test for STICs. Currently, women with germ line mutations in the BRCA 1/2 genes are counselled that risk reducing bilateral salpingo-oophorectomy should be performed as soon as childbearing is complete or by the age of 35 to 40 years, since the benefit diminishes with age. An effective screening test for STICs will hopefully allow high risk women to safely and with less anxiety defer risk reducing bilateral salpingo-oophorectomy until childbearing is completed or even until menopause, thereby preventing premature menopause. With adequate test performance women might even be spared from risk reducing bilateral salpingo-oophorectomy completely.
Individual patients will not benefit from participating in this study, nor will there be any burden, as the lavage will be performed prior to the surgery, when the patient is already under anaesthesia.

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

Prophylactic salpingo-oophorectomy in women with BRCA 1 or BRCA 2 mutations

Exclusion criteria

Pregnancy
A history of tubal occlusion

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Catheter for uterine and tubal lavage
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-10-2014
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02039388
CCMO	NL49519.091.14