Lavage of the Uterine Cavity for the Diagnosis of Ovarian and Tubal Carcinoma and Their Premalignant Changes. (LUDOC)

This study is currently recruiting participants. (see Contacts and Locations)

Verified June 2015 by Medical University of Vienna

Sponsor:
Medical University of Vienna

Information provided by (Responsible Party):
Paul Speiser, Prof.MD,, Medical University of Vienna

ClinicalTrials.gov Identifier:
NCT02062697

First received: January 20, 2014
Last updated: June 30, 2015
Last verified: June 2015
History of Changes

Purpose

Epithelial Ovarian cancer (EOC) is the leading cause of death among gynaecologic malignancies in western civilized countries, with an estimated prevalence in Europe and the US of 752,600 in 2007 and 59,828 deaths annually.

State-of-the-art diagnostic tests for EOC include transvaginal ultrasonography and serum cancer antigen (CA-125) measurements; the specificity of these diagnostic tools however is low, and both tests are not effective enough at detecting EOC early enough to improve clinical outcomes. Definitive diagnosis of EOC still relies on histological or cytological confirmation. These findings underline the importance for an effective test for early detection of EOC.

In the current project we will obtain a lavage of the uterine cavity. It will be investigated whether cells from EOCs or genetic material from those cells can be detected in the lavage fluid.

Aim of this study:

There is a clear clinical need for a diagnosis test to detect EOC at an earlier stage.

Condition	Intervention
Ovarian Epithelial Cancer	Procedure: Lavage of the Cavum uteri and proximal fallopian tubes Procedure: Liquid-PAP smear

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Diagnostic

Official Title: Pilot Study of the Lavage of the Uterine Cavity for the Diagnosis of Ovarian and Tubal Carcinoma and Their Premalignant Changes - **LUDOC** Study

Resource links provided by NLM:

MedlinePlus related topics: Cancer Ovarian Cancer

Genetic and Rare Diseases Information Center resources: Ovarian Cancer Ovarian Epithelial Cancer

U.S. FDA Resources

Further study details as provided by Medical University of Vienna:

Primary Outcome Measures:

- Detection of EOCs by mutation analysis in the lavage of the uterine cavity. [Time Frame: Day 1] [Designated as safety issue: No]

  If the adnexal tumor removed turns out to be an EOC, mutation analysis will be carried out applying the sensitive massively parallel sequencing method published by Kinde et al. Mutations in the following genes will be analysed: AKT1, APC, ARID1A, BRAF, CTNNB1, CSMD3, CDKN2A, EGFR, FBXW7, FAT3, FGFR2, KRAS, MLL2, NRAS, PTEN, PIK3CA, PIK3R1, PPP2R1A, PIK3R, RNF43, and TP53.

Secondary Outcome Measures:

- Detection of EOCs by mutation analysis of the liquid-based Pap smear. [Time Frame: Day 1] [Designated as safety issue: No]

Obtaining material from the uterine cervix by applying a liquid-based Pap smear technique to directly compare the two sampling techniques - Lavage and liquid-based Pap.

Estimated Enrollment:	50
Study Start Date:	February 2012
Estimated Study Completion Date:	December 2018
Estimated Primary Completion Date:	December 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Ovarian Epithelial Cancer • Lavage of the Cavum uteri and proximal fallopian tubes • Liquid-PAP (Papanicolaou) smear	Procedure: Lavage of the Cavum uteri and proximal fallopian tubes Other Name: MF 13005 (MADICOPLAST Catheter) Procedure: Liquid-PAP smear

Detailed Description:

Epithelial Ovarian cancer is the leading cause of death among gynaecologic malignancies in western civilized countries, with an estimated prevalence in Europe and the US of 752,600 in 2007 and 59,828 deaths annually. Treatment and survival of the patients depend primarily on the stage of the disease. Of all EOC patients only 25% are diagnosed at an early stage while the tumour is confined to the pelvis. In these cases the five-year survival rate is 80% to 90% and the disease can often be cured by the combination of surgery and chemotherapy. Unfortunately, almost 75% of women affected have advanced stage disease with metastatic spread throughout the abdominal cavity or to retroperitoneal lymph nodes at the time of diagnosis; five-year survival rates drop to 10%-30% for advanced disease, despite maximum surgical effort and combination chemotherapy.

State-of-the-art diagnostic tests for EOC include transvaginal ultrasonography and serum cancer antigen (CA-125) measurements; the specificity of these diagnostic tools however is low, and both tests are not effective enough at detecting EOC early enough to improve clinical outcomes. Definitive diagnosis of EOC still relies on histological or cytological confirmation. These findings underline the importance for an effective test for early detection of EOC.

In the current project we will obtain a lavage of the uterine cavity. It will be investigated whether cells from EOCs or genetic material from those cells can be detected in the lavage fluid.

Aim of this study:

There is a clear clinical need for a diagnosis test to detect EOC at an earlier stage.

Eligibility

Ages Eligible for Study:	18 Years to 80 Years
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- suspected ovarian cancer
- verified ovarian cancer

Exclusion Criteria:

- pregnant
- incapacitated persons

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02062697

Contacts

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Locations

Austria

Medical University Vienna, Dptm. of Obstetrics & Gynaecology — **Recruiting**
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Belgium

University Hospitals Leuven - Department of Obstetrics and Gynaecology — **Recruiting**

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Czech Republic

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Sponsors and Collaborators

Medical University of Vienna

Investigators

Principal Investigator:	Paul Speiser, Univ.Prof.Dr.	Medical University Vienna, Dptm. of Obstetrics & Gynaecology
Study Chair:	Robert Zeillinger, Univ.Prof.Dr.	Medical University Vienna, Dptm. of Obstetrics & Gynaecology, Molecular Oncology Group

More Information

No publications provided

Responsible Party:	Paul Speiser, Prof.MD,, Univ.Prof.MD., Medical University of Vienna
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Study First Received:	January 20, 2014
Last Updated:	June 30, 2015
Health Authority:	Austria: Ethikkommission

Keywords provided by Medical University of Vienna:
Neoplasms
Glandular and Epithelial
Ovarian Neoplasms
Ovarian cancer

Additional relevant MeSH terms:

Neoplasms, Glandular and Epithelial	Genital Neoplasms, Female
Ovarian Neoplasms	Gonadal Disorders
Precancerous Conditions	Neoplasms
Adnexal Diseases	Neoplasms by Histologic Type
Endocrine Gland Neoplasms	Neoplasms by Site
Endocrine System Diseases	Ovarian Diseases
Genital Diseases, Female	Urogenital Neoplasms

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