

Trial record **1 of 1** for: ludoc[Previous Study](#) | [Return to List](#) | [Next Study](#)**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

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[History of Changes](#)[Full Text View](#)[Tabular View](#)[No Study Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)**▶ 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)

<u>Arms</u>	<u>Assigned Interventions</u>
Ovarian Epithelial Cancer <ul style="list-style-type: none"> • 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:

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► 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

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Recruiting

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Sponsors and Collaborators

Medical University of Vienna

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▶ More Information

No publications provided

Responsible Party: Paul Speiser, Prof.MD., Univ.Prof.MD., Medical University of Vienna

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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

ClinicalTrials.gov processed this record on July 23, 2015