**Estrogen, Diet, Genetics and Endometrial Cancer**

This study is currently recruiting participants.
Verified by Memorial Sloan-Kettering Cancer Center, June 2008

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| Sponsors and Collaborators:  | **Memorial Sloan-Kettering Cancer Center**[National Cancer Institute (NCI)](http://clinicaltrials.gov/ct2/bye/7QoPWw4lZX-i-iSxuBc5udNzlXNiZiJ.)Cancer Institute of New JerseyMunicipal Institute of Medical Research[Department of Health and Human Services](http://clinicaltrials.gov/ct2/bye/CQoPWw4lZX-i-iSxlQoRu6c9cXE.) |
| Information provided by: | Memorial Sloan-Kettering Cancer Center |
| ClinicalTrials.gov Identifier: | NCT00587886 |

  Purpose

The purpose of this study is to see how people's diets, other aspects of their lifestyles, and their individual genetic makeup affect their chances of getting endometrial cancer (cancer of the uterus).

This survey will enroll several hundred women who have or have had endometrial cancer and several hundred who do not. We will compare these two groups of women to see what factors may lead to endometrial cancer.

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| [Condition](http://clinicaltrials.gov/ct2/help/conditions_desc)  | [Intervention](http://clinicaltrials.gov/ct2/help/interventions_desc)  |
| CancerEndometrial CancerOvarian CancerCorpus UteriEndometrium | Behavioral: Questionnaire |

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| [Genetics Home Reference](http://ghr.nlm.nih.gov/) related topics:    | [Benign Tumors](http://clinicaltrials.gov/ct2/bye/SQoPWw4lZXcilwpxudhWudNzlXNiZip90dcx5Q1PedcxowN9Lw4Lp67xe6cxWi7LZwUR.)   [Cancer](http://clinicaltrials.gov/ct2/bye/vQoPWw4lZXcilwpxudhWudNzlXNiZip90dcx5Q1PedcxowN9Lw4L0B7x061n.)   [Uterine Fibroids](http://clinicaltrials.gov/ct2/bye/LQoPWw4lZXcilwpxudhWudNzlXNiZip90dcx5Q1PedcxowN9Lw4LLihHSQ7xz6NzpwN9e6oR.)    |

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| [MedlinePlus](http://www.nlm.nih.gov/medlineplus/) related topics:    | [Cancer](http://clinicaltrials.gov/ct2/bye/uQoPWw4lZX-i-iSxudhWudNzlXNiZip9m67PvQ7xzwhaLwS90B7x061nuQoPmdt.)   [Ovarian Cancer](http://clinicaltrials.gov/ct2/bye/LQoPWw4lZX-i-iSxudhWudNzlXNiZip9m67PvQ7xzwhaLwS9ZiNGSQ7GuBcGuBcHSXNkWd7E.)    |

[U.S. FDA Resources](http://clinicaltrials.gov/ct2/info/fdalinks)

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| Study Type:   | Observational |
| Study Design:   | Case Control, Prospective |
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| Official Title:   | Estrogen, Diet, Genetics and Endometrial Cancer |

Further study details as provided by Memorial Sloan-Kettering Cancer Center:

Primary Outcome Measures:

* To investigate the role of weight, diet, and individual genetic susceptibility to endometrial cancer [ Time Frame: 3 years ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

* The secondary aim of this study is to obtain epidemiologic data on papillary serous and clear cell histologic types of endometrial cancer. [ Time Frame: 3 years ] [ Designated as safety issue: No ]

Biospecimen Retention:   Samples With DNA

Biospecimen Description:

Buccal specimen

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| Estimated Enrollment:   | 1400 |
| Study Start Date:   | September 2001 |
| Estimated Study Completion Date:   | December 2009 |
| Estimated Primary Completion Date:   | December 2009 (Final data collection date for primary outcome measure) |

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| [Groups/Cohorts](http://clinicaltrials.gov/ct2/help/arm_group_desc)  | [Assigned Interventions](http://clinicaltrials.gov/ct2/help/interventions_desc)  |
| Cases Cases will be women with newly diagnosed endometrial or ovarian cancer who are residents of six counties in New Jersey.  | Behavioral: Questionnaire The main questionnaire will cover established risk and protective factors for endometrial and ovarian cancer, as well as other possible risk factors. This includes: menstrual history; pregnancy history; use of hormones for menopausal symptoms or other reasons; smoking history; height and weight; use of oral contraceptives and other methods of birth control; family history of cancer; medical history; demographic characteristics. We will also collect dietary data using the Gladys Block questionnaire, to which we have added a supplement to measure consumption of phytoestrogens. We will also obtain a buccal sample from each respondent as the source of DNA for genetic analysis.  |
| Controls Controls will be selected from the general population in those counties by use of random digit dialing for those under 65 years of age, from Centers for Medicare and Medicaid Services (CMS) lists for those aged 65 years and over, and from neighborhood sampling.  | Behavioral: Questionnaire The main questionnaire will cover established risk and protective factors for endometrial and ovarian cancer, as well as other possible risk factors. This includes: menstrual history; pregnancy history; use of hormones for menopausal symptoms or other reasons; smoking history; height and weight; use of oral contraceptives and other methods of birth control; family history of cancer; medical history; demographic characteristics. We will also collect dietary data using the Gladys Block questionnaire, to which we have added a supplement to measure consumption of phytoestrogens. We will also obtain a buccal sample from each respondent as the source of DNA for genetic analysis.We will conduct interviews mainly by telephone but also in person (at home or another convenient place)if the participant prefers. |

Detailed Description:

We will conduct a population-based case-control study in six counties of New Jersey. Cases will be women with newly-diagnosed endometrial or ovarian cancer. Controls will be matched by 5-year age groups and selected by random digit dialing (for those under 65), from Centers for Medicare and Medicaid Services (CMS) files (for those 65 and over), or from neighborhood sampling. Controls will not have had a hysterectomy.

There will be 400 cases with endometrioid tumors, 60 with serous tumors or clear cell tumors, 300 with ovarian cancer, and 400 controls. In addition, there will be a small group of black women included from MSKCC.

We will interview participants about known and potential risk factors for endometrial and ovarian cancer and obtain information on diet. We will obtain DNA for genetic analysis from buccal specimens collected using a mouthwash rinse method. We will use logistic regression to determine odds ratios for disease with various exposures. For endometrial cancer, we will examine the association of risk with genotypes in strata defined by body mass index and dietary fat consumption.

  Eligibility

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| Ages Eligible for Study:    | 21 Years and older |
| Genders Eligible for Study:    | Female |
| Accepts Healthy Volunteers:    | Yes |
| Sampling Method:    | Probability Sample |

Study Population

In collaboration with the New Jersey Department of Health and Senior Services NJDHSS), we will use rapid case ascertainment to identify patients as they are diagnosed.For controls aged 65 and over, we will obtain lists from CMS of a sample of women in the 6 counties. As an alternative way of reaching controls, we will conduct area sampling.

Criteria

Inclusion Criteria:

* Diagnosed with epithelial endometrial or ovarian cancer within the year before being contacted (cases)
* Aged 21 and over
* Residents of Essex, Union, Morris, Middlesex, Bergen, or Hudson counties, NJ
* Black women with and without endometrial cancer who are seeing gynecologists at MSKCC

Exclusion Criteria:

* Unable to sign informed consent
* Consent withheld by physician (cases)
* Hysterectomy (controls)
* Do not speak English or Spanish

  Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00587886

Contacts

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| Contact: Sara Olson, PhD      |  | olsons@mskcc.org      |

Locations

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| United States, New York |
|  | Memorial Sloan-Kettering Cancer Center     |  | Recruiting |
|  |       New York, New York, United States, 10065  |
|  |       Contact: Sara Olson, PhD         olsons@mskcc.org      |

Sponsors and Collaborators

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| **Memorial Sloan-Kettering Cancer Center** |
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| [National Cancer Institute (NCI)](http://clinicaltrials.gov/ct2/bye/7QoPWw4lZX-i-iSxuBc5udNzlXNiZiJ.) |
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| Cancer Institute of New Jersey |
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| Municipal Institute of Medical Research |
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| [Department of Health and Human Services](http://clinicaltrials.gov/ct2/bye/CQoPWw4lZX-i-iSxlQoRu6c9cXE.) |

Investigators

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| Principal Investigator:      | Sara Olson, PhD      | Memorial Sloan-Kettering Cancer Center      |

  More Information

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| [Memorial Sloan-Kettering web site](http://clinicaltrials.gov/ct2/bye/8QoPWw4lZX-i-iSxmwcm0BSxZwNw/kC7Hmd-yeB7EJ8caZB7OmDcHWihHSQ7xUnoizBp3FQ1Pz)  This link exits the ClinicalTrials.gov site   |

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| Responsible Party:    | Memorial Sloan-Kettering Cancer Center ( Sara Olson, PhD ) |
| Study ID Numbers:    | 01-119, CA83918 |
| First Received:    | December 24, 2007 |
| Last Updated:    | June 2, 2008 |
| ClinicalTrials.gov Identifier:    | [NCT00587886](http://clinicaltrials.gov/ct2/show/NCT00587886) |
| Health Authority:    | United States: Institutional Review Board |

Keywords provided by Memorial Sloan-Kettering Cancer Center:

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| Cancer    |
| Endometrial cancer    |
| Ovarian cancer    |
| Corpus Uteri    |
| Endometrium    |

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Study placed in the following topic categories:

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| Ovarian cancer |
| Ovarian Neoplasms |
| Gonadal Disorders |
| Genital Neoplasms, Female |
| Endocrine System Diseases |
| Uterine Diseases |
| Urogenital Neoplasms |

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| Ovarian Diseases |
| Genital Diseases, Female |
| Endometrial Neoplasms |
| Uterine Neoplasms |
| Endocrinopathy |
| Endometrial cancer |
| Endocrine Gland Neoplasms |

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Additional relevant MeSH terms:

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| Neoplasms |
| Neoplasms by Site |
| Adnexal Diseases |

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ClinicalTrials.gov processed this record on July 09, 2008