NRG Oncology Clinical Trial: NRG-CC008 [SOROck]

A non-randomized prospective clinical trial comparing the non-inferiority of Salpingectomy to salpingo-Oophorectomy to Reduce the risk of Ovarian Cancer among BRCA1 carriers [SOROck]

About the trial

SOROck [NRG-CC008] is a clinical trial that is studying if removal of just the fallopian tubes with the plan to remove the ovaries at a later time can reduce the risk of ovarian cancer the same as the usual care of removing both the ovaries and fallopian tubes among pre-menopausal women inherited BRCA1 mutations. Researchers believe that most ovarian cancers first begin in the fallopian tubes, suggesting that removing only the fallopian tubes may be as good as removing both the fallopian tubes and ovaries in preventing the development of ovarian cancer while avoiding surgical menopause. This has never been formally tested in a clinical trial. The study will also look at how women on the study feel about their quality of life.

About NRG Oncology

As one of the five research groups in the National Cancer Institute’s (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types.

NRG Oncology’s extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI.

To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org.

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Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
Premenopausal women between the ages of 35 and 50 who have an inherited BRCA1 mutation and are planning to have surgery to reduce their risk of ovarian cancer.

Can I change my mind if I choose to take part in this study?
Yes. Taking part in this study is voluntary. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the medical options study?
Everyone taking part in this study will have some type of surgery to reduce the risk of ovarian cancer. Women in the study will choose one of two options:

- Have their ovaries and fallopian tubes removed at the same time.
- Remove just their fallopian tubes with a plan to remove the ovaries at a later time.

Removing the ovaries and fallopian tubes is the standard of care and has been shown to dramatically reduce the risk of ovarian cancer and decrease the risk of death in women with mutations. Removing the fallopian tubes only may also help to prevent ovarian cancer and this study will determine if decreases the risk of developing ovarian cancer the same as the usual care.

How long will I be in this study?
The surgical procedure will occur on a single day as chosen by you and your surgeon. You will be followed for up to 20 years to see if you develop ovarian cancer in the future. You will be asked to have an annual CA125 blood test and complete online surveys approximately once per year.

Are there side effects?
The surgical procedures are very standard and not themselves part of the research investigations. We are most interested in determining if removing only the fallopian tubes provides a similar level of ovarian cancer prevention as removing the fallopian tubes and ovaries. We expect that less than 3% of all 2262 participants will develop ovarian or primary peritoneal cancer after either surgery, but we need to make sure that cancer is not more common in women who only remove their fallopian tubes. Your doctor will review all of the potential side effects with you.

More Information
Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer. You may also call: 1-(800)-4-CANCER (1-800-422-6237).

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