# GOG 0215 - A Phase II Randomized Study of the Effect of Zoledronic Acid versus Observation on Bone Mineral Density of the Lumbar Spine in Women Who Elect to Undergo Risk-Reducing Surgery that Results in Removal of Both Ovaries

## What is a clinical trial?

Clinical trials are research studies in which people help doctors find ways to improve health. Each study tries to answer scientific questions and to find better ways to prevent, diagnose or treat diseases and their side effects. The purpose of this study is to look at the effects of zoledronic acid (Zometa®) on preventing bone loss in women who experience early menopause due to surgical removal of the ovaries.

## Who can join?

You may be eligible to join this study if you are at least 30 years old, at increased risk of ovarian cancer, and are planning to undergo surgery that will result in the removal of both your ovaries. For this study, you are considered at increased risk of ovarian cancer if:

- You, or a close relative, have a cancer-related mutation in either the *BRCA1* or *BRCA2* gene; or
- Two or more close blood relatives have had breast or ovarian cancer; or
- At least one close blood relative has had breast or ovarian cancer, and you are of Ashkenazi Jewish descent; or
- If you have had premenopausal breast cancer (or breast cancer diagnosed prior to age 50), and you are of Ashkenazi Jewish descent.

You may NOT be eligible for the study if:

- You already have evidence of low bone mineral density
- You are taking certain medications, including estrogen, progesterone, bisphosphonates (such as Fosamax), or steroid medications
- You have active dental problems, or recent dental or jaw surgery

## What will happen in this study?

If you participate in this study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer picks which group you will be in. You will have an equal chance of being placed in either group. Neither you, your doctor, nor the researchers will be able to choose which group you are in.

**Treatment Group**

If you are assigned to the treatment arm, you will receive an injection of zoledronic acid (Zometa®) every six months for a total of three treatments. The first injection will be given two to three months after you undergo surgical removal of both ovaries. Zoledronic acid is given as an injection into your vein for at least 15 minutes. You will also be asked to give blood samples, undergo a bone density test, and complete questionnaires at the time of enrollment and periodically throughout the 18 month study period.

**Observation Group**

If you are assigned to the observation arm, you will not receive Zometa®, but will be asked to give blood samples, undergo a bone density test, and complete questionnaires at the time of enrollment and periodically throughout the 18 month study period.

Participants in **both** the Treatment Group and the Observation Group will be asked to take daily calcium and vitamin D supplements by mouth, and be given information about maintaining bone health.

## What are my choices?

Your decision to participate (or not participate) in this study is completely voluntary. If you do take part, you may choose to leave the study at any time for any reason. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Instead of participating in a clinical trial, you may choose to discuss other treatment options with your physician, or you may choose not to have treatment. Please read over this brochure and talk to your doctor about this study and your other options for care.

## Is there any risk to me?

Zometa® may cause flu-like symptoms, nausea and fatigue, symptoms that usually resolve on their own after a day or two. Some less common side effects include coughing, rash, or headaches. There have also been rare instances of kidney problems and dental problems associated with Zometa ® use. You should thoroughly discuss the possible side effects of this or any treatment with your doctor before making a decision about participating in this study or about what type of treatment you will receive.

## What are the benefits to me?

You will receive regular bone density scans, which helps assess bone health, at no charge during this study. Although no direct benefits to your bone health are known at this time, we do know that the information from this study will help doctors learn more about zoledronic acid and its impact on preventing bone loss. This information could help women in the future who undergo menopause.

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Women who choose to have their ovaries removed before menopause will experience immediate menopause due to the loss of estrogen in the body. A lack of estrogen can cause a variety of side effects, one of which is bone loss. Substantial bone loss can lead to a higher risk of bone fractures. This study is being conducted to find out if a medicine called Zometa® (zoledronic acid) can prevent or decrease bone loss due to early menopause.

Gynecologic Oncology Group

www.gog.org

**FOR MORE INFORMATION ABOUT THIS STUDY, PLEASE CALL YOUR PHYSICIAN:**

# GOG-0215

# Searching for New Ways to Improve Bone Health after Surgical Menopause

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## Information for Patients

http://ovariancancer.gog199.cancer.gov/gog215