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 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 undergo 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 and are planning to undergo, or have undergone in the last 8 weeks, surgery that results in the removal of both your ovaries.

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 replacement therapy, bisphosphanates (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 group, 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 over about 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 group, 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, to engage in regular, weight-bearing exercise, and to avoid tobacco smoking. This is the current recommended treatment approach for women who are at increased risk of osteoporosis.

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 is also a possibility of an allergic reaction. 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 and regular follow-up to 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.

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 Surgery that Results in Removal of Both Ovaries

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

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 Surgery that Results in Removal of Both Ovaries

Information for Patients

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