

# Breast Cancer Prevention Study



[BRCApStudy.org](http://BRCApStudy.org)



Women with a *BRCA1* mutation have a 50-70% lifetime risk of developing breast cancer.

Join us to help make a difference.

The BRCA-P Study is an international research study for women (ages 25 to 55) who are born with a mutation (change) in one of their *BRCA1* genes. About 2,918 women from around the world will participate in the study. The main purpose is to find out if the study drug, denosumab, can decrease the risk of developing breast cancer compared to a placebo (inactive substance) in women with a *BRCA1* gene mutation.

## You may be eligible to participate in the BRCA-P study if you:

- Women who have a confirmed *BRCA1* gene mutation (variant)
- Are 25 to 55 years old
- Do NOT have a history of breast or ovarian cancer
- Are not pregnant or breastfeeding
- Have not had a mastectomy (removal of breast(s) by surgery)

You may also be asked to consider some optional studies.

**If successful, our study could give *BRCA1* mutation carriers a new option to reduce breast cancer risk without surgery.**

**Your participation may help us advance breast cancer research for your family and beyond!**

## If you are eligible and decide to join the BRCA-P study, you will be asked to:

- Have blood drawn while you are on the study for testing and research purposes (up to 4 tablespoons)
- Be given a small injection of denosumab or a placebo (inactive substance) under the skin every 6 months for 5 years
- Submit your mammogram when you enroll and after your first year in the study for the study team to see whether there is any change in your breast density
- Have regular follow-ups with your study doctor/medical team to check on your overall health and talk about any symptoms or side effects
- Follow-up with your study doctor yearly for up to 5 years after your last injection of denosumab or placebo
- Have a dental exam to make sure you don't have any infections in your mouth (denosumab can cause some dental side effects, especially severe in women with active mouth infection). If dental concerns are found, you may be asked to visit your dentist before enrolling in the study
- As recommended by the study, take calcium (500 mg) and vitamin D (400 IU) supplements daily for 5 years. Calcium and vitamin D are recommended for general bone health, and particularly for those taking denosumab

## Learn more

You can contact our national BRCA-P Study team at [BRCApStudy@dfci.harvard.edu](mailto:BRCApStudy@dfci.harvard.edu)

@BRCApStudy



The BRCA-P Study is conducted in the United States by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute (NCI). In the United States, the trial is co-led by a national breast cancer and cancer genetics expert, Dr. Judy Garber, from the Dana-Farber Cancer Institute. The global coordinator of this study is the Austrian Breast & Colorectal Cancer Study Group (ABCSC).

This study is funded by the United States Department of Defense (DoD) and is supported by the National Cancer Institute. The drug, denosumab, is provided by the company that makes it, Amgen Global, which also provides the placebo for the study. The Breast Cancer Research Foundation, the Gray Foundation and two patient advocacy organizations, FORCE and Tigerlily Foundation, are supporting the trial.

