The main purpose is to find out if the study medication, denosumab, can decrease the risk of developing breast cancer compared to a placebo (inactive substance) in women with a *BRCA1* gene mutation.

IF YOU ARE ELIGIBLE AND DECIDE TO JOIN THE BRCA-P STUDY, YOU WILL BE ASKED TO:

- Have a small injection of denosumab or a placebo (inactive substance) under the skin every 6 months for 5 years
- Have blood drawn annually for testing and research (up to 4 tablespoons)
- Submit your mammogram when you enroll and after your first year in the study for the study team to evaluate 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
- 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
- Take calcium and vitamin D supplements daily for 5 years

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

YOU MAY BE ELIGIBLE TO PARTICIPATE IN THE BRCA-P STUDY IF YOU:

- 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 both breasts by surgery)

You may also be asked to consider some extra "sub-studies."

LEARN MORE

You can contact your local study team.

<Insert Site Contact Name and Title>

<Insert Name of Site>

<Insert Phone Number >

<Insert Email address>

You can also contact our national BRCA-P Study team at 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 (ABCSG).

This study is funded by the United States Department of Defense and is supported by the National Cancer Institute. The medication, 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.