



Alliance A211102: Testing for Atypia in Random Periareolar Fine Needle Aspiration (RPFNA) Cytology After 12 months Metformin (1, 1-Dimethylbiguanide Hydrochloride) Chemoprevention versus Placebo Control in Premenopausal Women

Victoria Seewaldt, MD, Rebecca Sutphen, MD, Sandhya Pruthi, MD

City of Hope, SunCoast CCOP Research Base and Mayo Clinic

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We have developed the scientific framework, biomarkers, and strategies to test the ability of targeted agents to eliminate cytologic atypia in high-risk women. Using our combined proteomic/tracking tools, we can directly test in an individual woman: 1) for activated signaling pathways; 2) whether the prevention agent eliminates cytologic atypia; and 3) if not, we can then identify additional signaling pathways that can be targeted. The ability to test whether a prevention drug is working in an individual woman allows us to rapidly deliver targeted prevention tailored to an individual woman.

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Primary

- Test for the presence or absence of cytological atypia in RPFNA bilateral aspirates after 12 and 24 months (24 month is optional for placebo-only group for patients who remain on placebo arm and will not receive metformin) for women receiving metformin versus placebo control. The presence of cytological atypia means any atypia in any RPFNA specimen.

Secondary

- Use the Masood Cytology Index Score to test for the presence of cytological atypia or disappearance of cytological atypia in RPFNA bilateral aspirates after 12 months for both arms, and 24 months (24 month is optional for placebo-only group for patients who remain on placebo arm and will not receive metformin, and mandatory for crossover patients) for women receiving metformin 850 mg p.o. bid (metformin group).
- Compare Masood Cytology Score values at 0 and 12 months in right and left breasts from the same individual in the metformin and placebo group.
- Test the reproducibility of RPPM in duplicate RPPM determinations from individual RPFNA specimens.
- Correlate baseline RPPM values with presence of atypia (as measured by Masood Cytology Index Score) at month 12 and month 24 (month 24 optional for placebo-only group; for patients who remain on placebo arm and will not receive metformin) RPFNA.
- Determine the change in percent breast density from prior to the initiation of metformin or placebo treatment through therapy (i.e., at 12 and 24 months), and following therapy (i.e., 36 and 48 months).



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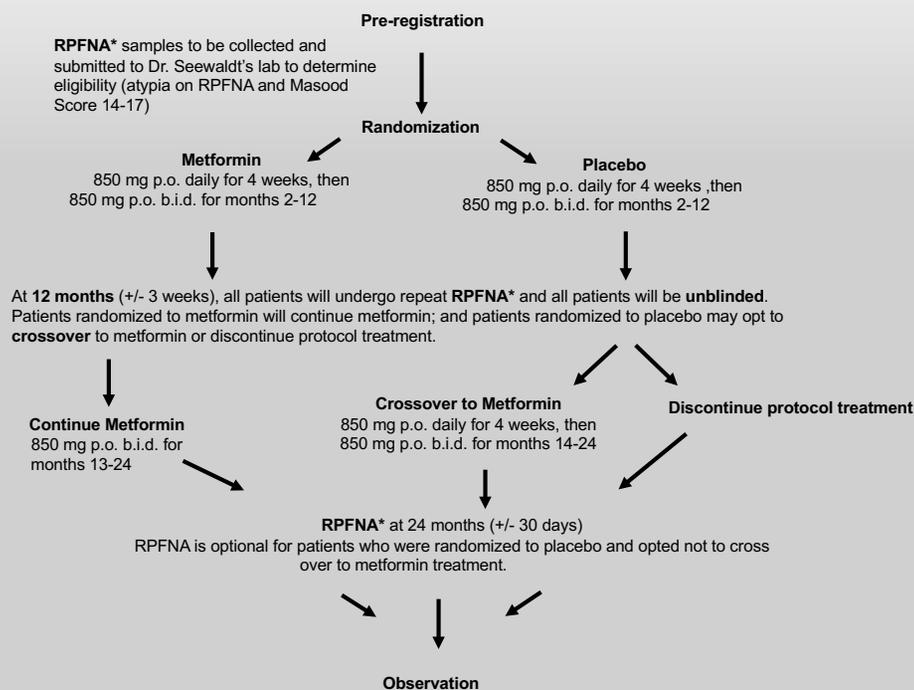
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Treatment Plan

- As a primary endpoint we will test for the presence or absence of cytological atypia in RPFNA bilateral aspirates after 12 and 24 months (24 month is optional for placebo-only group for patients who remain on placebo arm and will not receive metformin) for women receiving metformin versus placebo control. The presence of cytological atypia means any atypia in any RPFNA specimen.
- As secondary endpoints we will compare Masood Cytology Score values at 0 and 12 months in right and left breasts from the same individual in the Metformin and placebo group, test the reproducibility of RPPM in duplicate RPPM determinations from individual RPFNA specimens, and determine the change in percent breast density from prior to the initiation of metformin or placebo treatment through one year of therapy.

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Eligibility Criteria

Must be at increased risk for breast cancer, defined as at least one of the following four criteria:

- Having had a prior biopsy demonstrating atypical hyperplasia, lobular carcinoma *in situ* (LCIS), or ductal carcinoma *in situ* (DCIS).
- A Gail Model Risk of >1.66% over 5 years.
- A strong family history of breast and/or ovarian cancer which is defined as at least one of the following:
 - One first-degree relative with breast cancer before the age of 50 years
 - One first degree relative with bilateral breast cancer
 - Two or more first-degree relatives with breast cancer
 - One first degree relative and two or more second or third degree relatives with breast cancer
 - One first-degree relative with breast cancer and one or more relatives with ovarian cancer
 - Two second or third degree relatives with either breast cancer and one or more with ovarian cancer
 - One second or third degree relative with breast cancer and two or more with ovarian cancer
 - Three or more second or third degree relatives with breast cancer
- Known BRCA1 or BRCA2 mutation carrier providing that the woman has 1) met with a Genetic Counselor to review genetic testing results, and 2) has been offered the opportunity to undergo prophylactic mastectomy and oophorectomy.



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