Alliance A211601: Evaluation of Mammographic Breast Density Effect of Aspirin: A Companion Study to Alliance Study A011502

Marie Wood, MD
University of Vermont

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Rationale

This companion to A011502 will assess the changes in MD in the contralateral unaffected breast for patients with hormone receptor negative breast cancer enrolled on A011502 and correlate those changes with markers of inflammation. We have chosen to use this design (companion to an open and ongoing study) for several reasons:

1. Obtaining data from an ongoing study will provide important information regarding the potential for aspirin to act as a chemoprevention agent.
2. Use of the parent study is a valuable given the real world setting the study provides.
3. While there are multiple influences on mammographic density, mammography will continue to be used and this study will provide useful insight into influences on MD.

The primary endpoint will be mammographic breast density in the contralateral (unaffected) breast measured at one year. We will also assess MD at 2 years to explore both longitudinal change and the stability of mammographic density, particularly given that menstrual cycle cessation with chemotherapy may reverse over a longer period of follow up. This trial will be a necessary step in evaluating aspirin as a potentially active agent for prevention of this cancer sub-type.

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Objective

Primary

- To compare the 1-year mammographic breast density in the contralateral (unaffected) breast between the aspirin and placebo arms in patients with hormone receptor negative breast cancer enrolled in A011502.

Secondary

- To compare the 2-year mammographic breast density in the contralateral (unaffected) breast between the aspirin and placebo arms in patients with hormone receptor negative breast cancer enrolled in A011502.

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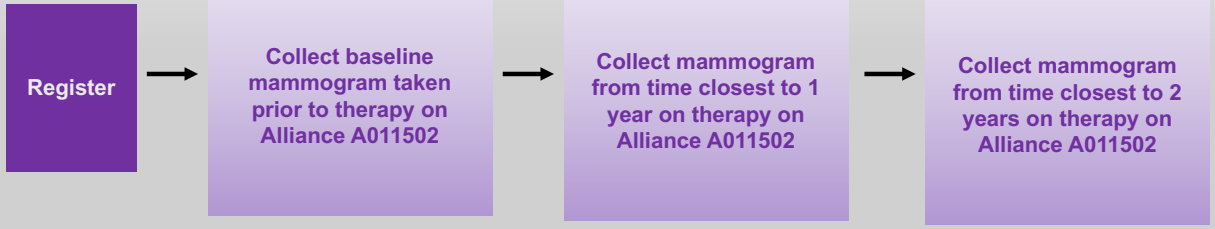
Study Schema



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Using Digital Mammography for Mammographic Density Analysis

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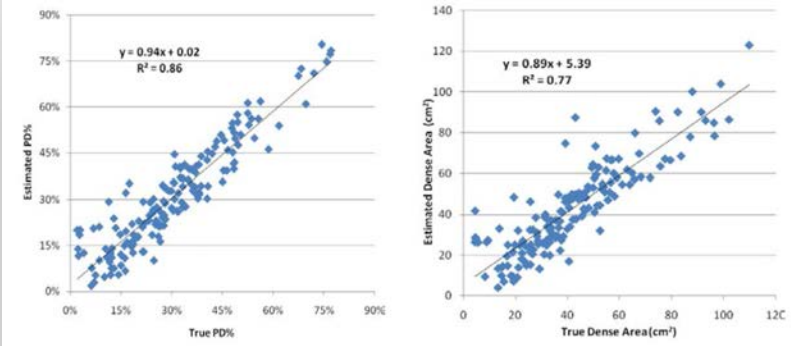

Figure 1. Validation of UPENN automated breast percent density (PD%) estimation algorithm versus the Yaffe & Boyd1 technique: Linear regression between (a) the breast PD% estimates and (b) absolute dense tissue values.

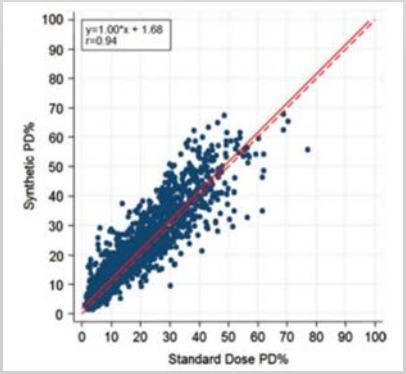

Figure 2: Percent Density comparison of synthesized vs standard 2D images.

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Eligibility Criteria

- Patients must be women concurrently enrolling to Alliance A011502. Eligible patients may be either pre- or post-menopausal.
- Patients must have hormone receptor-negative breast cancer.
- Patients must have baseline breast density measurement as defined by one of the following: 1) density, or 2) scattered areas of fibroglandular density, or 3) breast composition category b, c, or d, per BI-RADS 2013
- Baseline digital mammogram with a mediolateral (MLO) and craniocaudal (CC) view taken within 8 weeks prior to registration to this study must be available for submission.
- Patients receiving endocrine therapy (e.g., tamoxifen, aromatase inhibitors) are not eligible.
- Contralateral unaffected breast in place (with no prior cancer or radiation, no implants and no plan for breast surgery on contralateral breast over the course of the study). Patients with a prior biopsy on the unaffected breast are eligible.

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Funding Support

Alliance A211601 is funded by the National Institutes of Health through National Cancer Institute grant awards.

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