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Supplemental Table for:
Topical endoxifen for mammographic density reduction – a randomized controlled trial
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Supplemental Table 1

Inclusion criteria

To participate, the women must meet the following inclusion criteria:

- Participant in the Karma Cohort
- Attending the national mammography screening program, i.e., aged 40-74 and have performed a screening mammogram maximum 3 months prior to study inclusion
- Mammographic density ≥4.5 % density (volumetric) measured by Volpara, at the screening mammogram performed in connection to baseline (maximum 3 months prior to inclusion). The threshold value of 4.5% corresponds to the clinically used BI-RADS score A
- Postmenopausal, defined as no period of menstruation during last 12 months independent of any hormonal treatment
- Informed consent must be signed before any study specific assessments are performed

Exclusion criteria

To participate, the women must not meet any of the exclusion criteria listed below at entry of the study nor under time of treatment.

<u>Criteria related to study design</u>

- Any previous or current diagnosis of breast cancer (including carcinoma in situ)
- Any previous diagnosis of cancer with the exception of non-melanoma skin cancer and in situ cancer of the cervix
- A history of major surgery of the breast, e.g., reduction or enlargement, which might affect density measurements
- Mammographic BI-RADS *malignancy* code 3, or above, at baseline mammography, or at mammography during time of treatment. Recall for additional examinations due to technical problems with the mammogram is accepted.
- Currently using oestrogen and progesterone based hormone replacement therapy (oral or patches). Local treatment accepted (ex. Vagifem)
- Non-medical approved drugs against hot-flashes including phytooestrogen

<u>Criteria related to safety</u>

- A history of thromboembolic disease such as embolies, deep vein thrombosis, stroke, TIA or myocardial infarction.
- Known APC (Activated Protein C)-resistance, an inherited hemostatic disorder
- Women who have an increased risk of venous thrombosis due to immobilization, e.g., using wheelchair
- Known uncontrolled diabetes
- Hypertension at baseline, defined as systolic pressure higher than 140 mm Hg and diastolic higher than 90 mm Hg
- Prescribed and regular use of anticoagulants (defined as substances included in group B01A in the ATC-system)
- Non-medical approved drugs against hot-flashes including phytooestrogen
- Not able to understand study information and/or informed consent