

## RANDOMIZED NON-INFERIORITY TRIAL COMPARING OVERALL SURVIVAL OF PATIENTS MONITORED WITH SERUM TUMOR MARKER DIRECTED DISEASE MONITORING (STMDDM) VERSUS USUAL CARE IN PATIENTS WITH METASTATIC HORMONE RECEPTOR POSITIVE HER-2 NEGATIVE BREAST CANCER

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 18 years and over

This study is NOT accepting healthy volunteers

### Inclusion Criteria:

- diagnosis of hormone receptor positive (estrogen receptor positive [ER+] and/or progesterone receptor positive [PR+]), HER-2 negative, metastatic (M1) breast cancer - receiving or plan to receive first-line systemic treatment for metastatic disease - no other prior malignancy is allowed except for adequately treated basal (or squamous cell) skin cancer, in situ cervical cancer or other cancer for which the patient has been disease free for five years

### Exclusion Criteria:

- known cirrhosis, untreated B12 deficiency, thalassemia, or sickle cell anemia - known brain leptomeningeal metastases - must not be pregnant

### Conditions & Interventions

#### Interventions:

Other: Anxiety Questionnaire Administration, Other: Quality-of-Life Assessment, Other: Serum Tumor Marker directed disease monitoring, Other: Usual care disease monitoring

#### Conditions:

Cancer

#### Keywords:

Breast Cancer, Breast Cancer, Tumor Markers, Metastatic Breast Cancer

### More Information

**Description:** This study is looking at how well serum tumor markers work to monitor people who have hormone receptor positive Her2 negative breast cancer that has spread to other places in the body. We want to see if using the markers (from a blood sample) is as good as using scans to monitor disease.

**Study Contact:** Kristen Nelson - knelso65@fairview.org

**Principal Investigator:** Nicole Hartung

#### IRB

**Number:** MMCORC021

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