clinical studies

breast

Trial Of Preoperative Radiation (TOPAz)

A Randomized Trial Comparing Hypofractionated Versus Conventionally Fractionated Preoperative Radiation Followed by Mastectomy With Immediate Autologous Breast Reconstruction With Integrated Nanomechanical Biomarker Evaluation

PRINCIPAL INVESTIGATOR

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SITE ENROLLING

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ClinicalTrials.gov ID:
NCT05774678

artidis

Timely Diagnosis | Optimized Therapy

Phase 3 | Type: **Interventional** | Allocation: **Randomized** | Interventional Model: **Double Arm**
Masking: **Open Label** | Primary Purpose: **Treatment**

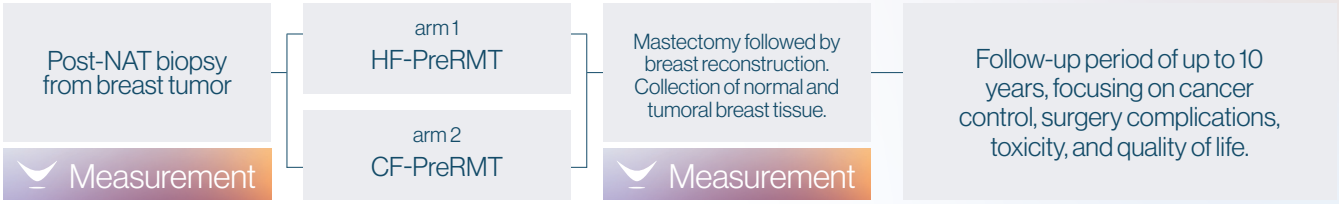
Brief Summary

To compare the outcomes of and responses to 2 different radiation therapy schedules (the standard radiation amount and number of doses versus less radiation and fewer doses) that are being given before having breast cancer surgery (cancer removal and reconstruction).

Clinical Relevance

The clinical relevance is to evaluate the safety, efficacy, and optimal dosing of pre-mastectomy hypofractionated regimens, as a means to reduce surgical complications, improve patient quality of life, and potentially enhance outcomes in breast cancer treatment. By evaluating the predictive power of the ARTDIS Nanomechanical Signature, it could guide the clinical strategy for effective radiation therapy dosing to improve response rate and minimize side effects thus improving patient quality of life.

Study Schema



Study Population

Patients diagnosed with invasive breast cancer before mastectomy who are undergoing preoperative radiotherapy.

No. of ptients: 126

Age: ≥18y

Study Duration & Read-Outs

Enrollment Start: Q2 2023

Expected duration: 2 years

Clinical Follow Up: 10 years

Key End-Point Readout

3 months
6 months
12 months

SPONSOR & PARTNERS

Sponsor
MD Anderson Cancer Center

Collaborator
Artidis AG

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Key Inclusion

- Age 18 years or older.
- Histologic diagnosis of invasive breast cancer.
- Clinical and/or pathologic stage T3-T4c OR N1-N3; for the IBC pilot cohort only, the stage requirement is T4d, any N, M.
- Mastectomy is the planned oncologic surgery but has not yet been performed at the time of protocol enrollment.
- Autologous (i.e. tissue-based) reconstruction is planned with either a free or rotational flap.
- For patients with HER2 positive, non-IBC breast cancer treated with neoadjuvant chemotherapy, one of the following criteria must be met: **A.** Residual invasive disease should be documented in either the breast or a regional nodal metastasis after neoadjuvant chemotherapy. This specific eligibility criteria can be satisfied by the post-chemotherapy standard of care breast biopsy. For this matter, the patient may be enrolled on the trial prior to biopsy. If the biopsy does not show residual invasive disease, then the patient will not proceed with protocol-directed therapy, and will be removed and replaced from the study. **B.** Medical oncologist has documented a discussion in the chart about potential risks of proceeding with PreMRT with regard to impact on adjuvant systemic therapy decisions and the patient has opted to proceed with trial enrollment 3.1.7 For T4d pilot cohort patients, post-chemotherapy, pre-radiation ultrasound must demonstrate at least partial response in the breast and regional lymph nodes and no suspicious infraclavicular, internal mammary, and supraclavicular lymph nodes.
- Ability to provide written informed consent in accordance with institutional policies.

Key Exclusion

- Patients undergoing treatment for recurrent breast cancer in the index breast or lymph
- History of therapeutic irradiation to the breast, lower neck, mediastinum or other area(s) that will overlap with the affected breast.
- Presence of active scleroderma.
- Patients who are pregnant.

Key Objectives

1. To compare BREAST-Q satisfaction with breasts 18 months after reconstructive surgery for patients randomized to HF-PreMRT versus CF-PreMRT. We hypothesize that HF-PreMRT will be superior to CF-PreMRT with regard to this endpoint.
2. To compare oncologic outcomes following HF-PreMRT versus CF-PreMRT, including residual cancer burden, local-regional control, disease-free survival, and overall survival.
3. To evaluate nanomechanical properties of the breast cancer before and after radiation and their association with oncologic outcomes.

Abbreviations: NAT - Neoadjuvant Treatment, Q2 - the second quarter of, BREAST-Q - Patient-Reported Outcome (PRO) Measure, IBC: Invasive Breast Carcinoma.

For any questions about this study or to express your interes in participating, please reach out to our research team at:

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