clinical studies

breast

Quantifying Temporal Immunologic Changes With Hypofractionated Radiation

Induced DNA Damage in Breast Cancer

PRINCIPAL INVESTIGATOR

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SITE ENROLLING

MD Anderson Cancer Center
Houston, Texas, USA

ClinicalTrials.gov ID:
NCT05406232

artidis

Timely Diagnosis | Optimized Therapy

Phase 2 | Type:Observational | Allocation: **Randomized** | Interventional Model: **Single Group Assignment**
Masking: **Open Label** | Primary Purpose **Treatment**

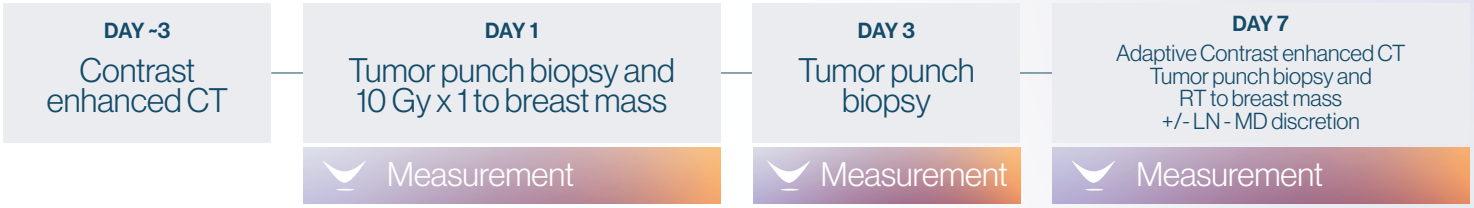
Brief Summary

This study assesses changes to the immune cells following hypofractionated radiation-induced DNA damage in breast cancer patients. Radiation therapy may cause immune cells to enter tumors and target cancer cells. The goal of this study is to measure the change in the level of immune cells in the tumor before and after radiation therapy.

Clinical Relevance

This study will provide better insight into how radiotherapy can stimulate antitumor immunity and synergize with immune checkpoint inhibitors to convert "immunogenically excluded or deserted" breast cancers into responders, ultimately improving patient outcomes. Findings will provide tissue evidence on how radiation therapy induced Nanomechanical Signature changes are associated with tumor stroma and immune cell infiltration.

Study Schema



Study Population

Female patients diagnosed with invasive breast cancer that appears to be superficially accessible to a tumor punch biopsy, undergoing hypofrationated radiation therapy (breast cancer patients who are not surgical candidates due to tumor bulk).

No. of patients
18

Age
≥18y

Study Duration & Read-Outs

Enrollment Start
Q4 2023

Expected duration
2 years

Clinical Follow Up
5 years

Key End-Point Readout

3 months
6 months
12 months

Key Inclusion

- Patients ≥ 18 years of age with biopsy proven invasive breast cancer of any histology
- Breast cancer that appears to be superficially accessible to a tumo punch biopsy.
- Patients thought to derive clinical benefit from palliative RT to the breast/chest wall.
- In discussions with the medical oncologist, if clinically reasonable, systemic therapy will be held during RT.

Key Exclusion

- A history of prior radiation to the area requiring radiation for which the attending physician believes reirradiation could not be safely delivered.
- Pregnancy.
- Active usage of anticoagulant medications that are considered to pos an increased risk of tumor punch biopsies.
- Receipt of immunotherapy or chemotherapy 7 days prior to start of RT.

Primary Objective

1. To estimate the percent change in immune infiltration at day 3 and day 7 of radiotherapy (RT) relative to baseline (before radiotherapy).

Secondary Objective

1. To estimate the degree of deoxyribonucleic acid (DNA) damage at approximately 3 and 7 days after radiotherapy compared to baseline.
2. To examine cancer cell intrinsic immune signaling following radiotherapy.

SPONSOR & PARTNERS

Sponsor
MD Anderson Cancer Center

Collaborator
Artidis AG

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Abbreviations: DNA - Deoxyribonucleic Acid, CT - Computed Tomography, RT - Radiotherapy, LN - Lymph Node, MD - Medical Discretion, Q4 - The fourth quarter of

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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