clinical studies

breast

Artidis Nanomechanical Generated Measurements for Early Breast Lesions (ANGEL)

PRINCIPAL INVESTIGATOR

Alastair Thompson, MD
Professor and Chief, Sec. of Breast Surgery
Baylor College of Medicine

SITE ENROLLING

Harris Health System
Houston, Texas, USA

ClinicalTrials.gov ID:
NCT06085833

artidis

Timely Diagnosis | Optimized Therapy

Clinical Performance Study | Type: **Interventional** | Design: **Prospective, Multicenter cohort study** | Allocation: **Not Randomized** | Interventional Model: **Single Arm** | Masking: **Blinded** | Primary Purpose: **Diagnostic & Treatment Optimization**

Brief Summary

This prospective, blinded, single-arm study aims to test the performance of nanomechanical signature in predicting tumor type, tumor aggressiveness, and neoadjuvant treatment response compared to the gold standard of histopathological assessment. The study involves patients with suspicious breast lesions who will undergo a breast biopsy procedure indicated by standard of care. The nanomechanical signature will be measured on the freshly obtained breast biopsies or tissue from breast surgeries.

Clinical Relevance

Breast cancer is the most prevalent cancer among women worldwide. While most cases are detected at localized stages, metastasis remains the leading cause of mortality. Early detection is critical for improving outcomes, minimizing invasive treatments, and enhancing overall survival and quality of life for patients. The nanomechanical signature biomarkers holds significant potential to enable rapid clinical decision-making and facilitate more effective treatment plans for breast cancer patients.

Study Schema

Standard of Care

Artidis ANGEL

Sample Size

1. System performance to detected malignant lesions.
2. System performance to rule out malignant lesions

No. of Patients

2,706

Eligibility Criteria

Inclusion Criteria

- Age 18 years or older.
- Ability to understand and the willingness to sign a written informed content.
- Indication for breast biopsy for diagnostic purposes.
- ECOG performance status of 0 to 3.

Exclusion Criteria

- Conditions that, in the investigator's opinion, might indicate that the subject is not suitable for the study.

Standard of Care (SOC) Biopsy

No additional biopsies required, no additional costs or burden of procedures for patients.

Including All Relevant Clinical Data

- Receptor status
- Menopausal status
- Tumor type and grade.
- DCIS status/LCIS status
- + additional clinical data

HR+/Her2-
Her2+
HR-/Her2-

Treatment & Response Data

- Details on all treatment lines
- NAT and Adjuvant, radiation etc.)
- Pathological complete response
- (pCR) by receptor status subtype
- Tumor size after neoadjuvant therapy
- Progression free survival (PFS)

SPONSOR & PARTNERS

Sponsor
MD Anderson Cancer Center

Collaborator
Baylor College of Medicine

PRINCIPAL INVESTIGATOR

Alastair Thompson, MD
Professor and Chief, Sec. of Breast Surgery
Baylor College of Medicine

Abbreviations: NAT - Neoadjuvant Treatment, ECOG - Eastern Cooperative Oncology Group Performance Status, DCIS - Ductal Carcinoma in Situ, LCIS - Lobular Carcinoma in Situ, pCR - Pathological Complete Response, SOC - Standard of Care, PFS - Progression Free Survival

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

communication@artidis.com
www.artidis.com
Basel · Houston · Barcelona

Information is consistent with ClinicalTrails.gov as of December 05, 2024. Products under investigation have not been approved for use outside of the clinical trial setting. This information is presented only for the purpose of providing an overview of clinical trials and should not be construed as a recommendation for use of any product for unapproved purposes.

 ISSUE DATE: 2025-11 VC-CP-001-v002