

clinical studies



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

SITES ENROLLING

Harris Health System

Houston, Texas, USA

MD Anderson Cancer Center

Houston, Texas, USA

UT Southwestern

Dallas, Texas, USA

Claraspital

Basel, CH

Vall d'Hebron

Barcelona, ES



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Timely Diagnosis | Optimized Therapy



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 signatures hold significant potential to aid in rapid clinical decision-making and facilitate more effective treatment plans for breast cancer patients.

Study schema



Sample size

- 1. System performance to detect malignant lesions.
- 2. System performance to rule out malignant lesions.

No. of patients
2,706

Eligibility criteria

Key inclusion criteria

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

Key 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)
- pCR by receptor status subtype
- Tumor size after neoadjuvant therapy
- Progression free survival (PFS)

SPONSOR & PARTNERS

Sponsor

Artidis AG

Collaborators

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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