clinical studies

breast

Evaluating Mechanical Properties of Post-Mastectomy Skin Flaps to Estimate Reconstruction Risks (EMPOwER)

PRINCIPAL INVESTIGATOR

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SITE ENROLLING

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ClinicalTrials.gov ID:
NCT06584396

artidis

Timely Diagnosis | Optimized Therapy

Clinical Performance Study | Type: **Observational** | Design: **Prospective, Single-Center Cohort Study**
Interventional Model: **Single Arm** | Masking: **Blinded** | Primary Purpose: **Diagnostic & Treatment Optimization**

Brief Summary

This study evaluates the skin and surrounding soft tissue that is removed during an implant reconstruction after a mastectomy.

Clinical Relevance

At present, there is no reliable biomarker to determine which patients are suitable for implant reconstruction, and more than 20% of all breast reconstructions fail, particularly after post-mastectomy radiation therapy. The Nanomechanical Signature as a biomarker for predict reconstruction failure, could allow the further optimization breast reconstruction strategies.

Study Schema

Patients post-mastectomy → Reconstructive surgery (Measurement) → Follow up: Reconstructive failure (Issues or complications leading to unsuccessful reconstruction)

Study Population

Female patients currently in the tissue-expander phase of reconstruction, with planned expander-to-implant exchange within 3 months.

No. of Patients: 110

Age: ≥18y

Study Duration & Read-Outs

Enrollment Start: Q3 2023

Expected duration: 4 years

Clinical Follow-Up: 2 years

Key End-Point Readout

12 months
24 months

Key Inclusion

- Age 18 years or older.
- Patient with history of mastectomy with tissue expander placement.
- Tissue expander in place at time of study enrollment
- Patient plans to undergo surgery to exchange tissue expander for permanent breast implant within the next 3 months of signing the informed consent.
- Ability to understand and provide written informed consent in accordance with institutional policies.

Key Objectives

1. Characterize the nanomechanical properties of the skin and adjacent soft tissue removed at the time of postmastectomy implant reconstruction.
2. Evaluate if the Nanomechanical Signature can predict the reconstructive surgery failure.

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Artidis AG

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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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