Randomized Feasibility Trial for Mesh in Pre-Pectoral Reconstruction

NCT05190978

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of California, Los Angeles
Enrollment	120 participants

Plain Language Summary

This study is testing whether using a surgical mesh during pre-pectoral breast reconstruction (implant placed in front of the chest muscle after mastectomy) offers any benefit compared to reconstruction without mesh. The goal is to determine the best technique for this increasingly common procedure.

You may be eligible if...
- You are a woman between 22 and 75 years old
- You are having a single or double mastectomy with immediate breast reconstruction using tissue expanders placed in front of the chest muscle (pre-pectoral)
- Both preventive and cancer-related mastectomies are accepted
- Nipple-sparing and skin-sparing techniques are both accepted

You may NOT be eligible if...
- Your surgeon finds the mastectomy skin flaps are too thin or unhealthy for immediate pre-pectoral reconstruction during surgery
- You are having one breast reconstructed in front of the muscle and the other behind it
- You are having a direct-to-implant reconstruction (skipping tissue expanders)
- You are pregnant
- You are having delayed reconstruction

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (3)

- Female patients age 22 to 75 undergoing unilateral or bilateral immediate pre-pectoral reconstruction with tissue expanders
- Prophylactic and oncologic mastectomies are both acceptable
- Nipple sparing and skin sparing mastectomy techniques are both acceptable

Exclusion (5)

- Intraoperative assessment demonstrates unfavorable conditions (ie poor mastectomy skin flap thickness or viability) for immediate pre-pectoral reconstruction in any breast
- Bilateral reconstruction patients undergoing contralateral submuscular reconstruction
- Direct-to-implant reconstruction
- Pregnancy
- Delayed reconstruction

Locations (1 total)

University of California Los Angeles, Los Angeles, California, United States

https://clinicaltrials.gov/study/NCT05190978