

# Same-Day Awake Mastectomy With Immediate Breast Reconstruction for Patients With Breast Cancer

NCT07510698

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	University of Rome Tor Vergata
<b>Enrollment</b>	100 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Biologically female participants aged 18 to 75 years
- Oncologic or prophylactic indication for nipple-sparing mastectomy or skin-sparing mastectomy with immediate prepectoral reconstruction using a definitive implant or tissue expander, including early breast cancer or a high-risk genetic condition such as BRCA
- Eligible for prepectoral reconstruction based on clinico-anatomic criteria, including adequate skin flap thickness, no relevant vascular compromise, body mass index less than 35, and no severe prior chest radiotherapy
- American Society of Anesthesiologists (ASA) class I to III
- Eligible for day surgery, defined by home autonomy, caregiver availability during the first 24 hours after surgery, and distance from the hospital compatible with home management

... and 2 more (see full listing online)

### Exclusion (7)

- Chronic opioid use or treatment for pre-existing chronic pain that could interfere with assessment of the primary postoperative pain endpoint
- Contraindications to locoregional anesthesia techniques or to the awake/monitored anesthesia care protocol, including allergy to local anesthetics, coagulation disorders, or inability to cooperate during surgery
- Body mass index 35 or greater, or anatomic conditions contraindicating prepectoral reconstruction
- Previous high-dose chest radiotherapy with significant tissue compromise
- Pregnancy or breastfeeding

... and 2 more (see full listing online)

## Locations (1 total)

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PTV Policlinico Tor Vergata University Hospital, Rome, Rome, Italy