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Comparison of two surgical techniques (Grisotti vs Wise pattern) for breast-conserving surgery in central breast cancer

Submission date
20/05/2025

Recruitment status
No longer recruiting

Registration date
28/05/2025

Overall study status
Completed

Last Edited
28/05/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at two different types of breast-conserving surgery used to treat women with breast cancer located near the nipple. These techniques aim to remove the cancer while preserving the appearance of the breast. The study compares the outcomes of the Grisotti technique and the Wise pattern technique to find out which provides better cancer clearance and cosmetic results.

Who can participate?
Women aged 35 to 75 years with centrally located, early-stage breast cancer who are suitable for breast-conserving surgery and have not had previous breast surgery or radiotherapy.

What does the study involve?
Participants were randomly assigned to receive either the Grisotti technique or the Wise pattern surgery. The results were assessed by examining whether the cancer was fully removed, if there were any complications, and how patients and surgeons rated the appearance of the breast after surgery.

What are the possible benefits and risks of participating?
All patients received standard breast cancer treatment. There may be improved understanding of which technique leads to better outcomes. Risks include standard surgical complications such as infection, seroma, or wound issues.

Where is the study run from?
Kasr Al-Ainy Teaching Hospital, Faculty of Medicine, Cairo University (Egypt)

When is the study starting and how long is it expected to run for?
March 2023 to November 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ahmed Shafik Jr, ahmed.shafik@ngu.edu.eg, shafikahmed@me.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Cairo University REC Approval Code: MD-266-2023

Study information

Scientific Title
Comparative outcomes of the Grisotti technique and its modifications in breast-conserving surgery: aesthetic and oncological implications

Acronym
COG-Wise

Study objectives
The Wise pattern technique provides superior aesthetic outcomes compared to the Grisotti technique in centrally located breast cancer, without compromising oncological safety.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 10/09/2023, Research Ethics Committee, Faculty of Medicine, Cairo University (Kasr Al Ainy Street, Cairo, 11562, Egypt; +20 (0)223651351; dean@kasralainy.edu.eg), ref: MD-266-2023

Study design
Prospective single-center randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Centrally located breast cancer (early-stage, operable)

Interventions
Participants were randomised in a 1:1 ratio using sealed opaque envelopes. The randomisation process was managed by a person independent of patient enrollment, surgical procedures, and outcome assessments.

Patients were randomly allocated to undergo one of two breast-conserving surgical techniques:
1. Grisotti flap technique
2. Wise pattern therapeutic reduction

Both procedures aimed to achieve clear oncological margins with acceptable aesthetic outcomes. Both patient- and surgeon-reported outcomes were assessed over a 12-month follow-up.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Margin status (tumor-free vs involved), assessed by pathology examination immediately post-surgery

Key secondary outcome(s))
1. Patient satisfaction measured using a 5-point Likert scale questionnaire at 3 and 12 months postoperatively
2. Surgeon-assessed aesthetic outcomes using a visual analog scale (VAS, 0–10) at 12 months postoperatively
3. Postoperative complications (seroma, infection, wound dehiscence) recorded clinically within 30 postoperative days
4. Tumor size and distance from the nipple-areola complex as documented in the pathology report at surgery

Completion date
15/11/2024

Eligibility

Key inclusion criteria
1. Female patients aged 35–75 years
2. Histologically confirmed centrally located breast cancer (T1–T2)
3. Tumor located within 2 cm of the nipple-areola complex
4. Suitable for breast-conserving surgery
5. Provided written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
75 years

Sex
Female

Total final enrolment
40

Key exclusion criteria
1. Non-central tumors (outside central quadrant)
2. Inflammatory breast cancer (T4d)
3. Metastatic disease
4. Multicentric tumors
5. Breast size smaller than cup size C
6. Prior breast surgery or irradiation

Date of first enrolment
15/10/2023

Date of final enrolment
15/09/2024

Locations

Countries of recruitment
Egypt

Study participating centre

Kasr Al-Ainy Teaching Hospital
Faculty of Medicine
Cairo University
Kasr Al-Ainy Street
Cairo
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Sponsor information

Organisation
Cairo University

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request from the corresponding author Dr Ahmed Shafik Jr (ahmed.shafik@ngu.edu.eg, shafikahmed@me.com). Data shared will be de-identified and limited to variables relevant to the reported outcomes.

Only aggregate data will be published in the manuscript. Individual-level data (e.g., patient satisfaction scores, surgeon ratings, complications) may be shared in an anonymized format upon request and subject to ethics approval.

Consent was obtained from participants for the use of their data in research, but not for open publication of raw data. Therefore, data will not be posted in a public repository but may be shared for academic collaboration, following institutional data-sharing protocols.

The data will be available from the time of publication and for up to 5 years. Requests will be considered on a case-by-case basis and must include a short data use proposal. No personally identifiable information will be released.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			28/05/2025	No	No