**WHO-Format Trial Protocol**

**Title:** Comparative Outcomes of the Grisotti Technique and Its Modifications in Breast Conserving Surgery: Aesthetic and Oncological Implications

**Principal Investigator:** Dr. Abdelrahman Lotfy
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**Collaborating Institution:** Faculty of Medicine, Cairo University (Kasr Al-Ainy Teaching Hospital)

**Background and Rationale:** Centrally located breast cancers represent a surgical challenge due to the involvement of the nipple-areola complex (NAC). Historically, these cases required mastectomy. Oncoplastic breast-conserving surgery (BCS) has expanded options for patients, allowing oncological safety with aesthetic preservation. The Grisotti technique and its Wise pattern modification offer two strategies tailored to different breast sizes. This trial seeks to compare their oncological and aesthetic outcomes.

**Objectives:**

- Primary: To compare margin status between Grisotti and Wise pattern techniques.
- Secondary: To compare complication rates, patient satisfaction, and surgeon-evaluated aesthetic outcomes.

**Trial Design:** Prospective, single-center, randomized controlled trial (RCT).

**Participants:**

- Inclusion: Female patients aged 35–75 with centrally located breast cancer (cT1–T2), eligible for BCS.
- Exclusion: Inflammatory, metastatic, multicentric tumors, or breast size < cup C.

**Setting:** Kasr Al-Ainy Teaching Hospital, Faculty of Medicine, Cairo University.

**Sample Size:** 40 patients (20 per group).

**Randomisation and Blinding:** Randomisation was performed using sealed opaque envelopes (1:1 ratio). Blinding was not feasible due to visible surgical differences.

**Interventions:**

- Group A: Grisotti technique (circular excision and NAC reconstruction using glandular flaps).
- Group B: Wise pattern therapeutic reduction (skin-sparing central lumpectomy with NAC reconstruction).

**Outcome Measures:**

- **Primary Outcome:**
    - Margin status assessed on final histopathology at time of surgery.
- **Secondary Outcomes:**
    - Patient satisfaction using a 5-point Likert scale at 3 and 12 months.
    - Surgeon-evaluated outcomes using a 10-point VAS at 12 months.
    - Postoperative complications (seroma, infection, dehiscence) within 30 days.
    - Tumor size and NAC distance from pathology reports.

**Statistical Analysis:** Data analyzed using t-tests, chi-square, and p-values $<0.05$ considered significant. Intention-to-treat analysis was performed.

**Ethical Considerations:** Approved by the Research Ethics Committee, Faculty of Medicine, Cairo University (Approval Code: MD-266-2023). Written informed consent obtained from all participants.

**Trial Registration:** Submitted retrospectively to ISRCTN (awaiting ID).

**Data Management and Sharing:** Data anonymized and stored securely. De-identified datasets available upon request.

**Dissemination Plan:** Results will be published in a peer-reviewed surgical oncology journal and presented at conferences.

**Timeline:**

- Ethics Approval: 10/09/2023
- Recruitment Start: 15/10/2023
- Recruitment End: 15/09/2024
- Study End: 15/11/2024

Code: MD-266-2023

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Cairo University
Faculty of Medicine
Research Ethics Committee

## NOTICE OF APPROVAL

Date: **10-9-2023**

Protocol title: **Comparative Study Between Grisotti Technique and its Modifications For Centrally Located Female Breast Cancer Candidate For Conservation and its Repercussion on Patients' Aesthetic Satisfaction and Oncological Outcome**

Supervisor: **Prof. Ismail Ahmed Shafik**

Candidate: **Dr. Muhammed Hussein Khalifa**

Institution: **Cairo University**

**Decision: APPROVAL**

The Research Ethics Committee **(REC)** has reviewed and **approved** the above-mentioned **protocol. You may begin your investigation**. Approval is granted for one year from the date of initial approval. At the end of this period, the principal investigator will submit the required documents for continuing review.

The principal investigator will need to:

- Notify the REC Chair immediately after any **serious adverse events** experienced by participants of the investigational study or as reported to you by the sponsor/manufacturer/co- investigators.
- Submit End of trial notification at the end of trial.
- Submit Clinical study report at the end of trial.
- You may not initiate **changes** in approved research protocol without REC review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.
- يحظر سفر أى عينات بشريه من المبحوثين خارج جمهوريه مصر العربية الا بعد موافقة الجهات الامنية .

**Sincerely,**

REC Chairman

**Prof. Maher Fawzy, MD**

Maher Fawzy

Professor of Anaesthesia.

Cairo University