PRO-TIGR-Matrix-PREPECTORAL-Trial

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Background

Implant reconstruction after breast removal is a common method of restoring the appearance of the breast. For many years, the subpectoral implant position was considered the gold standard. However, due to the advancement of technology, the current standard is the prepectoral position. Resorbable or non-absorbable meshes or acellular dermal matrices can be used in the reconstruction to stabilize the implant, fix it and preform a capsule. Meta-analyses have shown that neither the pre- nor the subpectoral position is an advantage for the patient in terms of complication rate. With regard to the use of meshes or matrices, there is still no head-to-head comparison between a mesh, an ADM or nothing. The aim of this study is to determine the patient-reported and cosmetic outcome, as well as the complications associated with the use of the fully absorbable TIGR mesh in the prepectoral implant breast reconstruction.

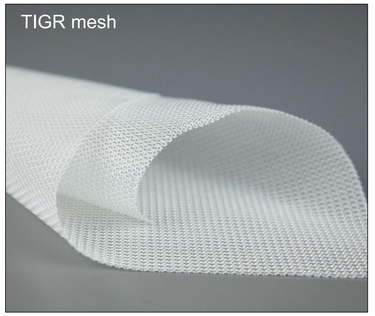
Trial Design

The PRO-TIGR-Matrix-PREPECTORAL study is a national, prospective, multicentre post market surveillance study on „Patient Reported Outcome“ of implant based primary or secondary reconstructive breast surgery after mastectomie using the complete resorbable synthetic Matrix (TIGR-Matrix, Novusscientific Sweden). The observation period is 3 years with a focus on patient reported satisfaction (as measured by BreastQ™), cosmetic outcome and complication rate. The study period will be 54 months, per patient: 36 months plus optional further follow-up surveys as part of the usual follow-up until the end of the study, recruitment phase will be 18 months, follow-up phase 36 months. 135 patients will be recruited.

Objectives

Primary endpoints: To assess quality of life after 12 months determined by the questionnaire BreastQ™.The study is considered successful, if and only if non-inferiority can be established for all four domains.

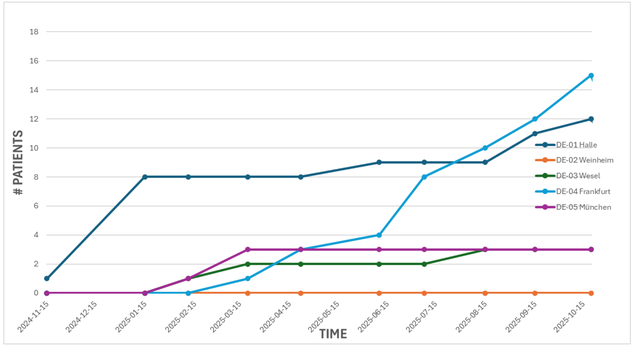
Secondary endpoints: Patient reported outcome/quality of life measured by BreastQ after 6, 24, and 36 months, the feasibility, efficacy, safety of the heterologous complete resorbable TIGR-Matrix in prepectoral implant-based breast reconstructive surgery. This includes the number and rate of occurrence of adverse events. Cosmetic result is reported by doctor and patient.



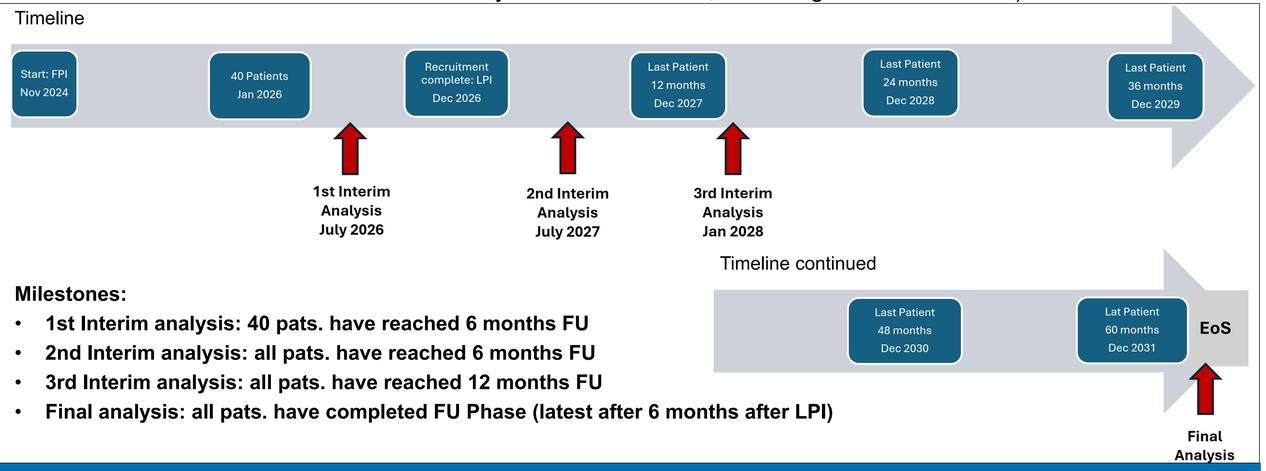
Measurements

Primary Measurements: Comparison of the pre- and post-op. (12 mon.) mean score of the BreastQ category "breast satisfaction" (well-being-breast); Patient-Reported-Outcome (PRO) measured with the specific questionnaire for breast reconstruction BreastQ 12 months after surgery.

Secondary measurements: Comparison of the pre- and post-op. (6, 12, 24, 26 mon.) mean score of the BreastQ category "breast satisfaction" (well-being-breast); Means scores of all BreastQ categories pre- and post-o.p after 6, 12, 24, 36 months. Complication rate: defined as major complications, minor complications; specific complications, such as seroma-volume, need for aspiration in symptomatic patients and number of aspirations in post-op. follow up, reconstructive failure (defined as unplanned implant loss), cosmetic outcome (domains of cosmesis of BreastQ) and rate of unplanned conversion operations (to mastectomy without reconstruction; to mastectomy with reconstruction; to autologous reconstruction).



Timeline



Milestones:

- **1st Interim analysis: 40 pats. have reached 6 months FU**
- **2nd Interim analysis: all pats. have reached 6 months FU**
- **3rd Interim analysis: all pats. have reached 12 months FU**
- **Final analysis: all pats. have completed FU Phase (latest after 6 months after LPI)**

Current Status (Oct. 2025)

33 patients are recruited. Planned sample size: 135 pts. up to 10. First Interim analysis planned: 40 evaluable patients with 6 months FU data available. No uncommon complications. 13 of 33 patients have reached the 6 months FU. Milestones: FPI Nov. 2024, 40 pats: Jan 2ß026, LPI: Dec 2026; **Sponsor:** AWOgyn, **Funding:** Novus Scientific

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