

(CINV) in early breast cancer (EBC) patients (pts) treated with anthracycline-based (neo)adjuvant chemotherapy {(N)ACT}.

Methods: We have planned the prospective observational study to assess the effectiveness and safety of primary prophylaxis with 4 drugs, FosNTP, PALO, DEX and OLZ, in a single-institution. The study is going to include 100 EBC pts with aged 20–74, who planned to be administered anthracycline-based (N)ACT. Based on the previously reported frequency of nausea with FosNTP, PALO and DEX and the noninferiority margin of 15%, the required number of cases was calculated to be 86 with the one-sided significance level of 5.0% and the power of 90%. Enrolled EBC pts rate the severity of CINV every 24 hours from the start of chemotherapy administration using visual analog scale. The primary endpoint is the no nausea rate within the acute and delayed phases at the first course of treatment.

Results: No data are available to present, as the study is still ongoing. We present the preliminary data from a retrospective review of CINV in 53 EBC pts in our institute.

Conclusions: For prophylaxis of CINV induced by highly emetogenic chemotherapy, several guidelines recommend the multiple use of targeted prophylactic drugs including neurokinin 1 receptor-antagonists (RA), 5-hydroxytryptamine-3 RA in combination with DEX, and OLZ. However, despite OLZ contribute to CINV prophylaxis owing to its antidopaminergic, antiserotonergic and anticholinergic properties, OLZ has some characteristic side effects such as somnolence that negatively impact the quality of life of EBC pts. The research question of our study is whether novel four-drug antiemetic therapy (FosNTP, PALO, DEX and OLZ) are effective for CINV prophylaxis.

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CINDERELLA Clinical Trial (NCT05196269): Patient Engagement with an AI-based Healthcare Application for Enhancing Breast Cancer Locoregional Treatment Decisions - Preliminary Insights

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Goals: False expectations and disappointments regarding the aesthetic outcomes of locoregional therapy are common challenges in breast cancer aftercare. The Breast Locoregional Outcome Artificial Intelligence (BreLO-AI) system was developed to visualise possible surgical outcomes, addressing these concerns. BreLO-AI has been integrated into a holistic digital health solution evaluated within the ongoing international CINDERELLA Trial. In this approach, the newly developed CINDERELLA patient app is of central importance. The trial investigates the app's ability in supporting informed locoregional treatment (LRT) decisions and enhancing understanding and satisfaction with aesthetic outcomes. The system allows retrieval of anonymised information about app usage, aiming to improve the go-to-market process and create a clinically validated digital tool for shared LRT decisions tailored to patients' needs. This work examines patient engagement and app usage during the trial's first 15 months.

Methods: The CINDERELLA patient app was specifically developed for this trial by an international multidisciplinary team including breast cancer and AI experts. The app was designed to serve as an information centre for patients, using personalised LRT information with AI-driven aesthetic outcome visualisations. The multimedia educational content was created by breast cancer experts and translated into 6 languages, allowing for different levels of information accessible for the user. The case report form and app were designed to allow the recording of app usage (login frequency, session duration, navigation behaviour) for demographic analyses.

Results: By October 21, 2024, 687 participants were enrolled, with 340 assigned to the intervention group (median age 53 years, median follow-up 5.6 months). Users spent an average of 33.7 minutes in the app, with a median of six logins. Post-surgery month-1 retention rate was 68.7%. Age-related differences in app usage were observed: patients under 40 used the app for 22.4 minutes on average, those aged 40–60 for 49.7 minutes, and those over 60 for 54.5 minutes (Kruskal-Wallis test, $p=0.01$). Nonetheless, most users were still active at the time of this analysis, so the user behaviour can only be evaluated provisionally.

Conclusions: The CINDERELLA app demonstrates good engagement and retention. The CINDERELLA trial is still recruiting and will conclude in 2026, providing a wide range of in-depth information on how breast cancer patients use digital health solutions.

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Exploring the Role of Precision Medicine in Adjuvant Systemic Therapy for Early-stage Breast Cancer: A Prospective Cohort Study

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Goals: The objective of performing the current investigation was to assess the effectiveness and toxicity of individualized adjuvant systemic therapy for patients with early-stage breast cancer with special reference to genomic markers for treatment decisions. We plan to establish whether the therapy individualized by biomolecular markers and molecular subtypes can enhance survival, decrease relapse, and decrease the toxic effects in contrast with standard treatments.