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Sentinel lymph node biopsy versus no axillary surgery in early breast cancer clinically and ultrasonographically node-negative: A prospective randomized controlled trial – venus trial early results after 3.5 years of study inception

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Objective: The VENUS trial is an ongoing prospective, multi-center, non-inferiority randomized controlled clinical trial aimed at comparing the disease-free and overall survival of T1-2 N0 M0 breast cancer patients subjected to either (a) sentinel lymph node (group sentinel) or (b) no axillary surgery (group no-sentinel). This is a partial report on the initial data collected 3.5 years after the trial started. VENUS differs from previous similar trials in that women undergoing mastectomy and neoadjuvant chemotherapy are accepted. **Methodology:** The protocol was approved by the local research ethics committee (CAAE: 068051 18.2.0000.5404). Initial axillary status was ascertained through physical examination and axillary ultrasound. Randomization is being stratified by age and clinical tumor size. Secondary endpoints include regional recurrence-free survival, axillary recurrence rate, axillary morbidity rate, ultrasound accuracy, and cost-effectiveness. The sample size was estimated at 800 participants. Primary and secondary endpoints will be reported after 5 years of follow-up of the completed cohorts. VENUS trial is registered in Clinical Trials (Identifier: NCT05315154) and ReBEC (Identifier: RBR-8g6jbf). **Results:** As of February 2023, 176 patients were enrolled and 156 were randomized to the sentinel (84 patients) and no-sentinel (72 patients) groups. The current mean follow-up time is 18.57 (+8.52) months. Patients are statistically evenly distributed across study groups regarding age and molecular subtype. Sentinel lymph node positivity in the sentinel group was 17.8% (1.19% isolated tumor cells, 3.57% micrometastasis, 11.90% 1–3 macrometastasis, and 1.19% > 4 macrometastasis). There were no axillary recurrences in both groups. **Conclusion:** Until now, with nearly 20% of the trial completed, VENUS showed no significant difference regarding its posted objectives in women undergoing or not sentinel lymph node dissection.

Keywords: breast neoplasms; breast cancer; sentinel lymph node biopsy; ultrasonography.