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# Is it possible to omit axillary surgery after neoadjuvant therapy for breast cancer? Preliminary outcomes in patients who underwent neoadjuvant treatment in the ongoing venus trial – a randomized controlled clinical trial

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**Objective:** Axillary surgery omission after neoadjuvant therapy (NAT) in breast cancer (BC) has not yet been studied. VENUS (ClinicalTrials.gov NCT05315154, ReBEC RBR-8g6jbf, Ethics approved: CAAE: 06805118.2.0000.5404) is an ongoing trial that evaluates the omission of sentinel lymph node biopsy (SLNB) in early BC and allows the inclusion of patients submitted to NAT. The aim of this study was to present preliminary axillary outcomes in patients submitted to NAT and compare them with patients referred to upfront surgery in the VENUS trial. **Methodology:** This is a multicenter, prospective, non-inferiority, open, randomized controlled clinical trial that includes women with stage T1/T2, N0 (clinical/ultrasound) M0 BC, randomized to SLNB or no axillary surgery. The initial treatment could be NAT or up-front surgery, based on local protocol at each study center. After NAT, axillary ultrasound should also be negative before randomization. **Results:** Up to 4.5 years after the VENUS trial started, 322 women were randomized. NAT was performed in 8% (n=26), of which 12 were randomized to SLNB (neoSLNB group) and 14 to no axillary surgery. Breast overall pCR rate was 39.1%. In the neoSLNB group, 41.7% had triple negative, 8.3% HER2, 25% luminal HER, and 25% luminal vs. 1.3%, 1.9%, 9.5%, and 87.4%, respectively, in the upfront surgery group ( $p<0.001$ ). The mean tumor size was 2.3 cm in the neoSLNB vs 1.5 cm upfront surgery group ( $p<0.001$ ). In the neoSLNB group, there were 8.3% of axillary positivity (1/12) and 20.9% (28/134) in the upfront surgery group ( $p<0.05$ ). So far, there has been no axillary recurrence (mean follow-up of 20 months). **Conclusion:** Patients submitted to NAT had larger and more aggressive tumors than patients in the upfront surgery. Axillary positivity after NAT was lower than in patients referred to upfront surgery. Until now, there have been no axillary recurrences in the VENUS trial.

**Keywords:** node-negative breast cancer; sentinel lymph node dissection; axillary staging; axillary surgery omission.