TAILORED AXILLARY SURGERY WITH OR WITHOUT AXILLARY LYMPH NODE DISSECTION FOLLOWED BY RADIOTHERAPY IN PATIENTS WITH CLINICALLY NODE-POSITIVE BREAST CANCER (TAXIS): A MULTICENTER RANDOMIZED PHASE-III TRIAL.


• Axillary lymph node dissection (ALND) has been standard treatment for breast cancer (BC) patients for almost a century.
• With the advent of the sentinel lymph node (SLN) procedure, ALND came under increasing scrutiny due to its association with significant patient morbidity.
• Randomized controlled trials (RCTs)1,2 have shown that in selected clinically node-negative SLN-positive patients, ALND can be safely omitted.
• Clinically node-positive patients, by contrast, continue to undergo ALND in many cases, if only for the lack of studies re-assessing the indication for ALND in these patients.
• TAXIS will fill this knowledge gap, by examining the value of Tailored Axillary Surgery (TAS), a new technique for selectively removing positive lymph nodes.3

Inclusion / Exclusion criteria
• Breast cancer, node positive detected by palpation or imaging (with or without planned neoadjuvant treatment)
• Female or male aged ≥ 18 years
• No stage IV breast cancer
• No clinical N3 breast cancer
• No prior axillary surgery
• No prior radiotherapy

Background

References

Study design

Primary endpoint: Disease-free survival (DFS)
Secondary endpoints:
• Quality of Life
• Arm morbidity
• Overall survival
• Breast cancer-specific survival
• Time to local recurrence
• Time to distant recurrence
• Physician-reported morbidity outcomes (Lymphedema)

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Current Status

Date of activation: 31.07.2018
Sites opened for accrual: 19 (CH)
Further sites planned: 5 (CH), 10 (AT), 3 (HU), 3 (IT)
Expected primary analysis: Q3 2029
Expected closure for accrual: Q1 2024

TAXIS is an international, multicenter, phase-III, non inferiority RCT, including 40 sites in 4 countries. 1500 patients will be randomized to either receive TAS followed by ALND and regional irradiation (excluding the dissected axilla) or receive TAS followed by regional nodal irradiation (including the full axilla).

Methods

Arm A
Stage IIIB breast cancer primary tumor ALND is planned (pN0/1 or T3/4)
No ALND
No ALND
Adjacent system's treatments
Breast/chest wall and regional nodal irradiation
Arm B
Stage IIIB breast cancer primary tumor ALND is planned (pN0/1 or T3/4)
No ALND
Adjacent system’s treatments
Breast/chest wall and regional nodal irradiation, including axilla

*Axillary Lymph Node Dissection (ALND) will usually be performed within the same procedure, however a second procedure for ALND at a later time point is allowed
# If indicated
‡If indicated administration of anti-HER2 treatment and endocrine therapy

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