

Synopsis

NIS Code: NIS-OCN-ARI-2010/1

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Study title:

A Prospective, Multicenter, Non-interventional Study Evaluating the Quality of Life of Postmenopausal Patients with Early Breast Cancer Positive for Hormone Receptors Treated with Adjuvant Therapy with Aromatase Inhibitors: 24-month Summary Analyses

Participating sites:

21 sites across Chinese mainland.

Study duration:

40 months

Date of First Subject Enrolled: June 2010

Date of Last Subject Completing Observation: October 2013

Objective:

The primary objective of this study was to evaluate the quality of life of postmenopausal patients with early breast cancer positive for hormone receptors treated with adjuvant therapy with aromatase inhibitors, as assessed by the change from baseline to 24 months in the FACT-B TOI.

Study design:

Prospective, multicenter, non-interventional study

Inclusion criteria:

Patients who:

- (1) Signed Informed Consent Form;
- (2) Were postmenopausal women aged ≤ 70 years;
- (3) Had histologically documented early breast cancer positive for hormone receptors ;
- (4) Were currently receiving initial adjuvant endocrine therapy with aromatase inhibitors, and had the indication approved by the SFDA for aromatase inhibitors;
- (5) Started adjuvant therapy with aromatase inhibitors within the last 7 days;
- (6) Understood the trial-related documents

Exclusion criteria:

Patients who:

- (1) Were unwilling to participate in this study;
- (2) Could not adhere to the trial requirements for any reason (e.g., mental disorder or neurasthenia);
- (3) Were using the aromatase inhibitor not approved by the SFDA for initial

adjuvant endocrine therapy for early breast cancer.

Number of subjects:

500 subjects were planned to be enrolled, 494 were actually enrolled, and 486 were included in the ITT set.

Efficacy variables:

Primary efficacy variable: change from baseline to 24 months in the FACT-B TOI;

Secondary efficacy variables: changes from baseline to 6 months, 12 months, 18 months and 24 months in the FACT-B Trial Outcome Index (TOI); changes from baseline to 6 months, 12 months, 18 months and 24 months in the FACT-B Emotional Wellbeing Subscale (EWB); changes from baseline to 6 months, 12 months, 18 months and 24 months in the FACT-B Social motional Wellbeing Subscale (SWB)

Safety variable:

Not applicable.

Efficacy assessment criteria:

Not applicable.

Statistical methods:

No statistical hypothesis was made as this was a descriptive study. The demographics of the enrolled patients were summarized and listed. The primary analyses of quality of life were based on the ITT population and included all the questionnaires collected. The MIXED model incorporated in the SAS software (SAS Institute, Cary, North Carolina) was used for analyses. This model allows handling of missing data without requiring entering the missing values (assuming a random data missing). All the baseline variables, e.g., the TOI, prior chemotherapies (With/Without), age group, mastectomy (With/Without) and axillary lymph node dissection (With/Without), were included in this model regardless of the statistical significance. Repeated measurement analyses also included time since baseline (as the fixed and random polynomial effects), so that the patient-specific tendency and intercept regarding time (described as random effects) changed around the total mean tendency and intercept (described as fixed effects). The results were presented as the adjusted means with the relevant confidence intervals, and the P values. The changes from baseline in mean scores were calculated for each patient with valid baseline questionnaires.

Results:

1. Primary efficacy variable analyses—change from baseline to 24 months in the FACT-B Trial Outcome Index (TOI)

The mean FACT-B TOI was 90.69 and 98.72 points at baseline and at 24 months, respectively, contributing to an 7.51 points increase from baseline to 24 months.

In the MIXED model, baseline TOI, visit, prior chemotherapies, age group and axillary lymph node dissection presented statistically significant effects on the change of FACT-B TOI; mastectomy presented no statistically significant effects on the change of FACT-B TOI.

The group with prior chemotherapies presented the mean change from baseline 8.88 points greater than in the group without prior chemotherapies; the age group >60 years presented the mean change from baseline 2.99 points greater than in the age group ≤60; the group with axillary lymph node dissection presented the mean change from baseline 3.55 points less than in the group without axillary lymph node dissection.

2. Secondary efficacy variables analyses

Changes from baseline to 6 months, 12 months and 18 months in the FACT-B TOI

The mean FACT-B TOI was 90.69, 94.36, 97.71, and 96.75 at baseline, 6 months, 12 months, and 18 months, respectively, contributing to the increases from baseline 3.58, 7.03, and 5.18 at 6 months, 12 months, and 18 months, respectively.

Changes from baseline to 6 months, 12 months, 18 months and 24 months in the FACT-B EWB

The mean FACT-B EWB was 16.32, 16.55, 17.34, 17.47, and 17.85 at baseline, 6 months, 12 months, 18 months, and 24 months, respectively, contributing to the mean increases from baseline 0.18, 1.03, 0.90, 1.36 at 6 months, 12 months, 18 months, and 24 months, respectively.

In the MIXED model, baseline TOI, visit, prior chemotherapies presented statistically significant effects on the FACT-B EWB; age group, mastectomy and axillary lymph node dissection presented no statistically significant effects on the FACT-B EWB. The mean change from baseline was 1.60 points greater in the group with prior chemotherapies than in the group without prior chemotherapies.

Changes from baseline to 6 months, 12 months, 18 months and 24 months in the FACT-B SWB

The mean FACT-B SWB was 18.61, 19.14, 19.35, 18.32, and 18.40 at baseline, 6 months, 12 months, 18 months, and 24 months, respectively, contributing to the mean changes from baseline 0.54, 0.75, -0.45, and -0.19 at 6 months, 12 months, 18 months, and 24 months, respectively.

In the MIXED model, baseline TOI, visit, prior chemotherapies, age group and axillary lymph node dissection presented statistically significant effects on the FACT-B SWB; mastectomy presented no statistically significant effects on the FACT-B SWB.

3. Safety analyses

Not applicable.