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Comparison patient-reported outcomes (PROs) between the continuation and stop groups after 5 years of anastrozole: NSAS-BC 05

Comprehensive Support Project

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Introduction

Five-year adjuvant aromatase inhibitor is standard for postmenopausal ER-positive breast cancer, however the effectiveness of endocrine therapy beyond 5 years has been demonstrated when there is a switch from tamoxifen to aromatase inhibitor. It is also known that patients with ER-positive breast cancer have a certain frequency of recurrence even after 5 years. Therefore, extension of adjuvant aromatase inhibitor for postmenopausal ER-positive breast cancer to 10 years is being attempted.

In National Surgical Adjuvant Study of Breast Cancer (N-SAS BC) 05 trial , preventive effect against late recurrence and safety of extending anastrozole further 5 years are evaluated in patients who had completed 5-year adjuvant anastrozole. Case registration ended in November 2012, and 1697 patients were registered. Disease-free survival as the primary endpoint will be evaluated in 2018.

The assessment of Health-Related Quality of Life (HR-QOL) was limited to about 300 patients who were registered from the start of case registration in November 2007 until November 2009. In this study, the change in patient-reported outcomes (PROs) between the continuation and stop groups was compared from baseline after 1 year.

Study Design: UMIN000000818

Postmenopausal women with breast cancer who completed 5-year treatment with anastrozole after surgery

(Including patients who received a total of 5-year treatment consisting of tamoxifen for 2 to 3 years, followed by anastrozole)

Randomization

Stratification Factors
- ◆Category of Adjuvant ET
- ◆Previous Chemotherapy Yes/No
- ◆Lymph node status
- ◆Institution

STOP n=849
No treatment for 5 years
(no additional medication)

CONTINUE n=848
Continuation of anastrozole
(1 mg/day) for 5 years

Study status: Active, Not recruiting
The primary endpoint will be analyzed on 2018.

HR-QOL assessment
The time for registration: November, 2007 to November, 2009
The patients with QOL data registered after 1year. **n=290**

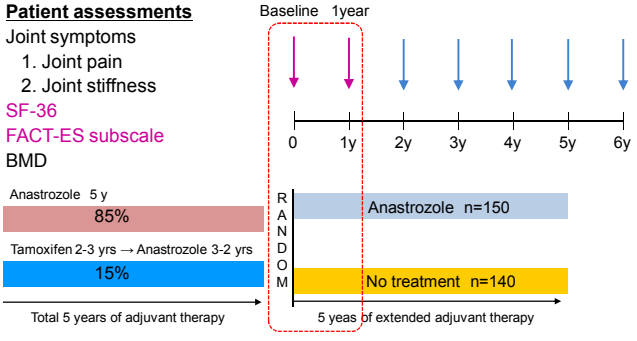
Study Endpoints

- Primary Endpoint
  - –Disease-free survival(DFS)
    Estimated sample size for DFS as primary endpoint: 1697 pts in total
- Secondary Endpoints
  - –Overall survival(OS)
  - –Distant-disease-free survival(DDFS)
  - –Adverse events, HR-QOL, Cost & benefits
- Other endpoints
  - –Bone mineral density
  - –Joint symptoms

QOL Assessment Schedule

Patient assessments
Joint symptoms
1. Joint pain
2. Joint stiffness

SF-36
FACT-ES subscale
BMD



Survey Items of Self-administered Questionnaires

Short Form 36-item Health Survey (SF-36)

FACT-ES sub-scale

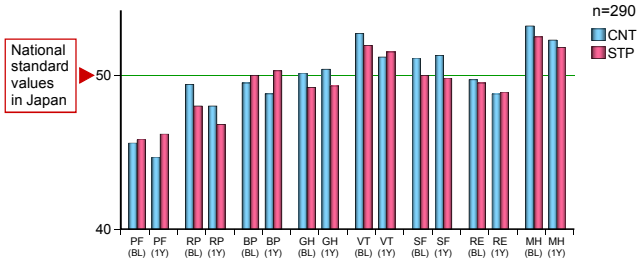
Patient characteristics

n=290

At time of registration	Mean	Min	Max
Age (years)	64.6	47	80
Height (cm)	153.1	131	168
Weight (Kg)	54.5	37	91
BMI (kg/m^2)	23.2	16.4	37.3
Duration of previous adjuvant endocrine therapy (day)	1810	1719	1902

There was no significant difference between the groups

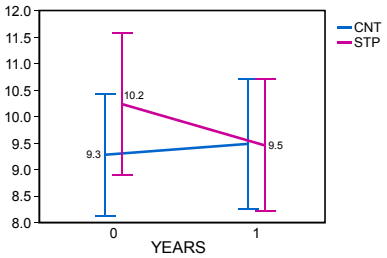
SF-36



In the SF-36 scale profiles, rolephysical (RP), vitality (VT), role-emotional (RE), and mental health (MH) showed slight decreases in both groups, physical functioning (PF) and bodily pain (BP) in the continuation group, and social functioning (SF) in the stop group. No differences were seen between the groups in any changes of the scores.

PF: Physical Functioning, RP: Role Physical, BP: Bodily Pain, GH: General Health, VT : Vitality, SF: Social Functioning , RE: Role Emotional, MH: Mental Health, (BL): Base line, (1Y): 1year

FACT-ES Change in total score



The sub-scale score of FACT-ES showed a slight decrease only in the stop group, but there was no significant difference between the groups in the change or the scores.

Conclusions

After 5 years of anastrozole administration, its continuation did not have an adverse impact on HRQOL compared with stop as assessed at 1 year. We plan to assess HRQOL annually until after 6 years.

Study Group
National Surgical Adjuvant Study of Breast Cancer

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