



Comparison of bone health in continuation and stop groups after 5 years of anastrozole: NSAS-BC 05



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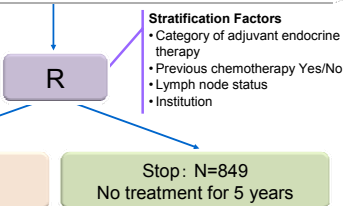
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Introduction

- Five years aromatase inhibitor is a standard adjuvant endocrine therapy for women with estrogen receptor positive breast cancer.
- Although 10 years of adjuvant tamoxifen was reported to be superior to 5 years of that by an EBCTCG meta-analysis, it remains to be clarified whether more than 5 years of adjuvant aromatase inhibitor may be superior to 5 years of that.
- National Surgical Adjuvant Study of Breast Cancer (N-SAS BC) 05 trial aims to analyze the efficacy of another 5 years adjuvant anastrozole (ANA) in Japanese women with breast cancer who completed 5 years of adjuvant endocrine therapy. The 5 years adjuvant endocrine therapy consisted of 5 years ANA or at most 3 years TAM followed by ANA.
- In the present study, bone health was analyzed from entry to 1 year, and it was compared between patients in the continuation group and stop group.

Study Design

• Postmenopausal women with invasive breast cancer who completed 5-year adjuvant anastrozole (ANA)
 • Including patients who received a total of 5-year treatment consisting of an initial tamoxifen (TAM) for up to 3 years, followed by ANA.

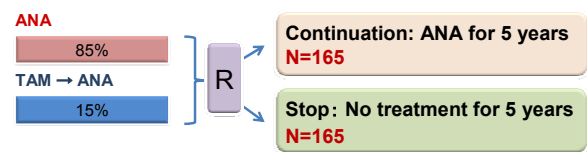
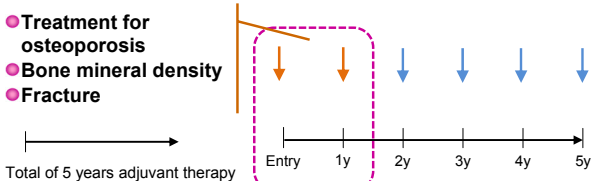


- Patient recruitment ended in November 2012, with 1,697 patients recruited.
- Efficacy analysis is to be conducted in 2018.

Endpoints

- Primary endpoint**
 - Disease-free survival (DFS)
- Secondary endpoints**
 - Overall survival (OS)
 - Distant-disease-free survival (DDFS)
 - Adverse events
 - Health-Related Quality of Life (HRQOL)
- Other endpoints**
 - Bone health
 - Joint symptoms

Bone Health Assessment



Age, Height, Weight, and Body Mass Index at Entry

	Continuation	Stop	P
Age (Years)	64.1 +/- 6.86	65.0 +/- 7.50	0.22
Height (cm)	153.0 +/- 6.36	153.4 +/- 5.54	0.53
Weight (Kg)	55.0 +/- 8.72	54.6 +/- 8.53	0.70
BMI (Kg/m ²)	23.5 +/- 3.49	23.2 +/- 3.33	0.44
No. Pts with BMI ≥ 25	49 (30%)	37 (22%)	0.13

BMI, Body Mass index

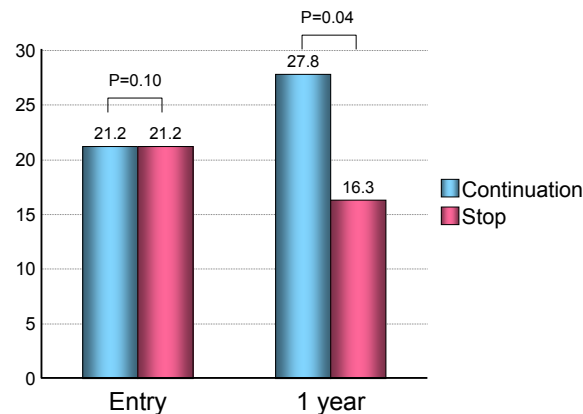
Previous Adjuvant Chemotherapy at Entry

	Continuation	Stop	P
Yes	99 (60%)	105 (64%)	0.50
No	66 (40%)	60 (36%)	

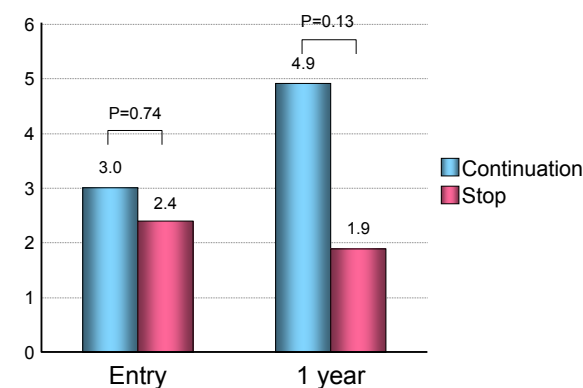
Osteoporosis Drugs at Entry

	Continuation	Stop	P
Any drugs	35 (21%)	35 (21%)	1.0
Bisphosphonate			0.88
Yes	25 (15%)	26 (16%)	
No	140 (85%)	139 (84%)	
Vitamine D			0.24
Yes	17 (10%)	11 (7%)	
No	148 (90%)	154 (93%)	
Other drugs			0.47
Yes	3 (2%)	5 (3%)	
No	162 (98%)	160 (97%)	

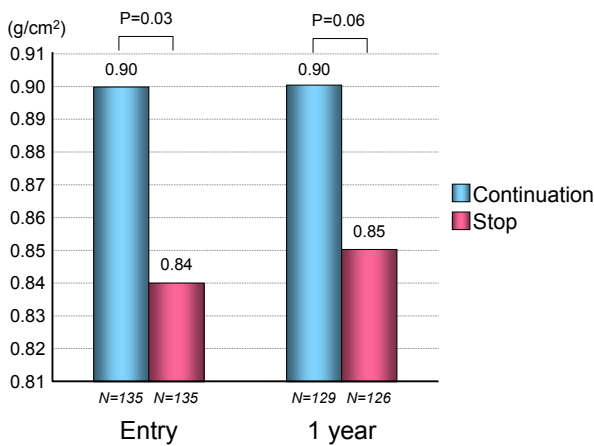
Frequency (%) of Taking Any Osteoporosis Drugs



Frequency (%) of Taking Non-steroidal Antiinflammatory Drugs

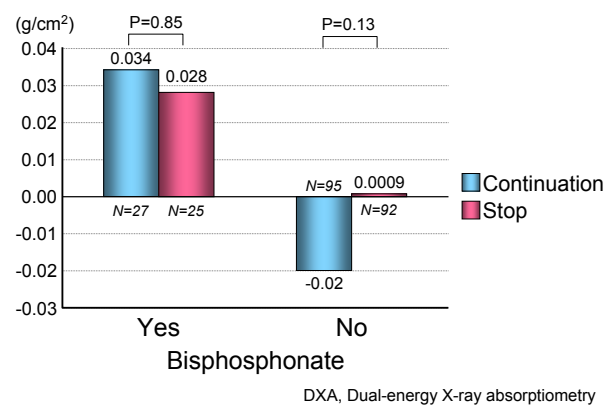


Bone Mineral Density (by DXA)



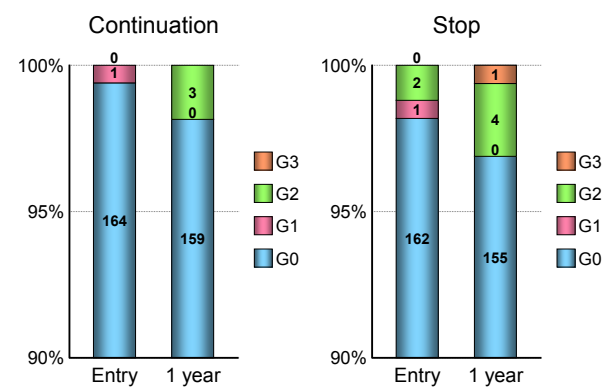
DXA, Dual-energy X-ray absorptiometry

Change in Bone Mineral Density (by DXA) Stratified by Use or Non-use of Bisphosphonate



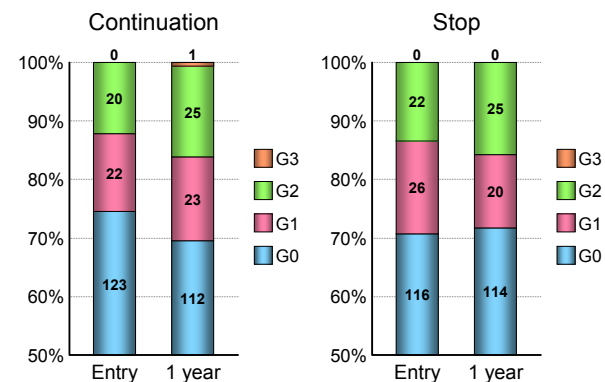
DXA, Dual-energy X-ray absorptiometry

Fracture (CTCAE Grade)



- No significant difference was found between the continuation group and stop group at entry and 1 year.

Osteoporosis (CTCAE Grade)



- No significant difference was found between the continuation group and stop group at entry and 1 year.

Summary

- Treatment for osteoporosis**
 - The number of patients receiving any treatment for osteoporosis at entry was the same in the 2 groups.
 - The number increased from entry to 1 year in the continuation group and decreased in the stop group.

- Bone Mineral Density**
 - The change in BMD from entry to 1 year was not significantly different between the 2 groups when analyzed separately for the presence and absence of bisphosphonate use.
 - However, continued ANA tended to decrease BMD in patients using no bisphosphonate.

- Fracture**
 - Any fractures at any sites were found at 1 year after entry in 1.9% of subjects in the continuation group and 3.1% in the stop group, and no statistically significant differences were found.

Conclusion

- Additional adjuvant anastrozole is safe in terms of bone health for 1 year after the completion of 5 years of adjuvant anastrozole in Japanese postmenopausal women with breast cancer.