A PROSPECTIVE RANDOMIZED MULTI-CENTER OPEN-LAB
Ⅲ TRIAL OF EXTENDING AROMATASE-INHIBITOR ADJUVA
TO 10 YEARS - RESULTS FROM 1697 POSTMENOPAUSAL
THE N-SAS BC 05 TRIAL:
ARIMIDEX EXTENDED ADJUVANT RANDOMIZED STUDY (A

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December 4-8, 2018

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Baseball America (181

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DISCLOSURE SLIDE

Shoichiro Ohtani 2e. Fees for Non-CME Services Received Directly from Commercial Interest or their Agents : Chugai,

Shigehira Saji 2d. Consulting Fees: Astra Zeneca, Chugai, Novartis, Pfizer
2e. Fees for Non-CME Services Received Directly from Commercial Interest or their Agents : Astra Zeneca, Chugai, Novartis, Takeda, Pfizer
2f. Contracted Research :Chugai, Novartis, Takeda

Hiroshi Ohtsu 2d. Consulting Fees :Deloitte Tohmatsu Consulting LLC, Public Health Research Foundation

Hirofumi Mukai 2e. Fees for Non-CME Services Received Directly from Commercial Interest or their Agents : AstraZeneca, Pfizer Japan , Chugai and Taiho Pharmaceutica l
2f. Contracted Research: Ono Pharmaceutical, Eli Lilly and Merck & Co.

This study was funded by the Comprehensive Support Project (CSP) of the Public Health Research Foundation. The corporate and individual sponsors of this study are listed on the CSPOR website (http://www.csp.or.jp/cspor/kyousan_e.html). The pharmaceutical manufacturer/distributor who provided financial contributions as a corporate sponsor took no part in this study except providing information relevant to the proper use of the study drug(s).

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Background

- Treatment with an aromatase inhibitor (AI) for 5 years as up-front monotherapy or afte therapy for 2-3 years is the treatment of choice for hormone-receptor-positive breast c in postmenopausal women.
- Extending endocrine therapy is an important treatment of choice for reducing the risk c breast cancer recurrence.
- Recently, DATA, IDEAL, MA17R, and NSABP B42 trials showed that extended AI ther the occurrence of secondary breast tumors. However, they had no or only a small imp
- Several studies investigated the safety and efficacy of additional treatment with AIs aft a sequential regimen of tamoxifen and AI for 5 years. Only the AERAS study investiga the safety and efficacy of the same AI between for 10- and 5-years treatments.
- Extension of treatment with an aromatase inhibitor to 10 years may reduce the risk of breast cancer recurrence.

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N-SAS BC 05(AERAS) study design

Postmenopausal women with primary breast cancer who had received 4 years 9 months to 5 years 2 months of adjuvant therapy with anastrozole

Amendment; postmenopausal women who had received tamoxifen and then received anastrozole for more than 2 years, a total of 5 years of adjuvant therapy, were also allowed.

Stratification Factor
- Nodal status
- Prior adjuvant chemotherapy
- Choice of tamoxifen or anastrozole
- Institution

Registration
Randomization
1:1

STOP GROUP
NO EXTENDED USE OF anastrozole

CONTINUAL GROUP
EXTENDED USE OF anastrozole for an additional 5 years

FOLLOW UP (median follow up period:4.9Y)

1697 Patients Randomized in ITT, Nov 2007-Nov 2012

Primary endpoint : DFS

Secondary endpoints:
- OS
- DDFS
- Safety
- HRQOL
- Cost-effectiveness

UMIN : 000000818

Statistical Consideration

- We designed this study to detect an increase in 5y-DFS rate fror in stop group to 94% in continual group, based on previous stud
- A statistical power of 80% and a two-sided α level of 0.05 requir participants, accounting for about a 10% dropout
- Primary and secondary endpoints were assessed by stratified lo rank tests and controlling for stratification variables
- Hazard ratios and corresponding 95% CIs were calculated base stratified Cox proportional hazards model

Patient Demographics and Disease

		STOP GROUP (N=843) n(%)	CONTINUAL GROUP (N=840) n(%)
Median age	Years	64.5	64.3
BMI		23.3	23.3
T-stage	T1	437 (51.8)	449 (53.4)
	T2	378 (44.8)	358 (42.6)
	T3/T4	28 (3.3)	33 (3.9)
N-stage	N0	667 (79.1)	650 (77.3)
	N1	163 (19.3)	171 (20.3)
	N2	13 (1.5)	19 (2.2)
Hormone receptor	ER +	836 (99.1)	830 (98.8)
	PgR +	627 (74.3)	618 (73.5)

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Patient Demographics and Disease Characteristics (2)

		STOP GROUP (N=843) n(%)	CONTINUAL GROUP (N=840) n(%)
Radiotherapy	Yes	457 (54.2)	456 (54.2)
	No	383 (45.4)	385 (45.8)
Adjuvant chemotherapy	Yes	332 (39.3)	328 (39)
	N0	509 (60.3)	512 (60.9)
Endocrine therapy In first 5 years	TAM→ANA	76(9)	75(8.9)
	ANA	772 (91)	774 (91.1)

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Duration of Study Treatment

- Median duration of treatment was 4.9 years in both groups
- Overall, 75.2% of patients in STOP group and 70.1% of p in CONTINUAL group completed 5 years of study treatm

Reason of early termination	STOP GROUP (%)	CONTINUAL GROUP (%)
Adverse events	0	9.6
Patient refusal	3	7.4
Changing hospital	2.2	2.2
Breast cancer recurrence	11.3	5.4
Second cancer (not breast-related)	5.4	1.9
Other	4.1	2.9

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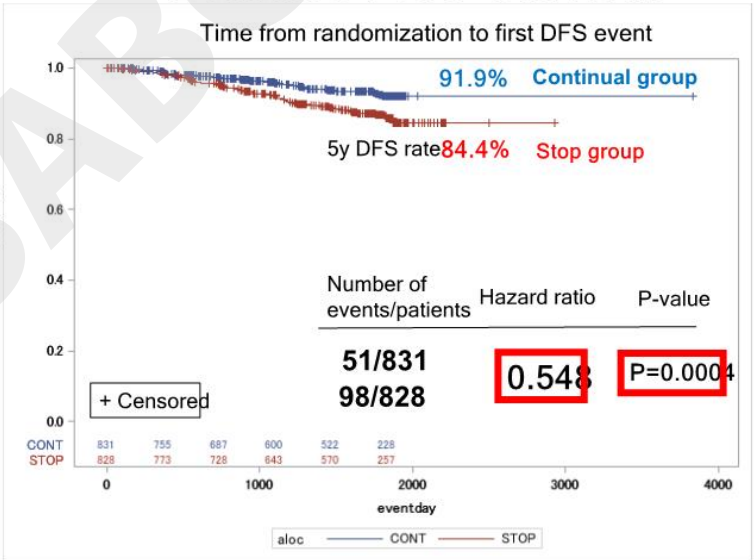
Disease-Free Survival



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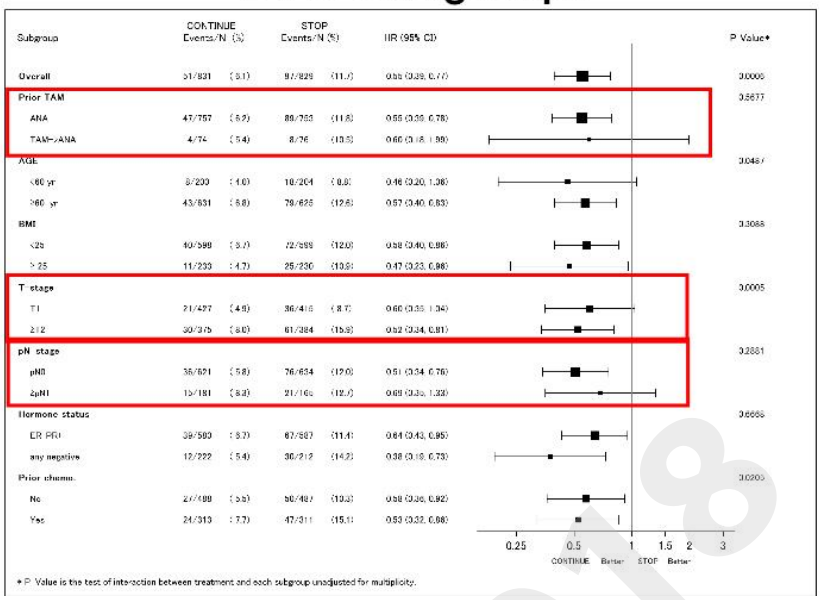
DFS Subgroups



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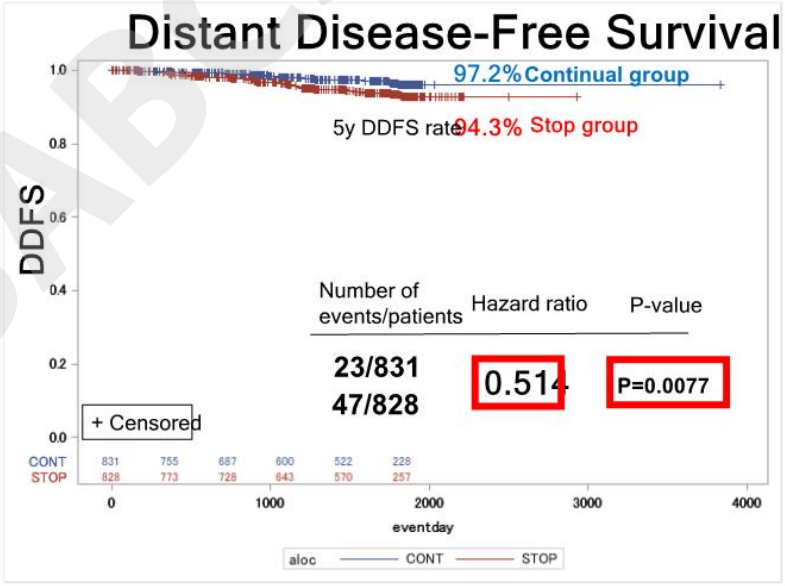
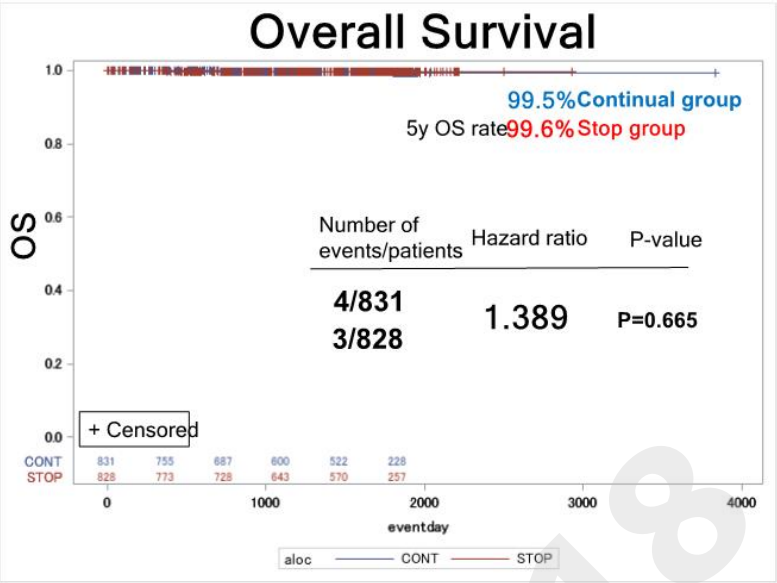
Distant Disease-Free Survival



Overall Survival



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ALL Events

	STOP GROUP (n=828)		CONTINUAL GROUP (n=831)	
	No. of Pts	%	No. of Pts	%
Local recurrence	32	3.8	15	1.8
Distant recurrence	47	5.6	23	2.7
Contralateral breast cancer	7	0.8	6	0.7
Second primary Cancer	35	4.3	13	1.5
Death	3	0.3	4	0.4

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Predefined Adverse Events

	STOP GROUP (N=783)		CONTINUAL GROUP (N=783)	
	Any	Grade≥3	Any	Grade≥3
Bone fractures	1.1%	0.1%	2.8%	0.5%
Osteoporosis	2.8%	0.1%	3.3%	0.3%
Arthralgia	11.7%	0.1%	19.2%	0.8%
Stiff joints	4.9%	0%	11.7%	0.3%
Hot flashes	3.2%	0%	6.7%	0.5%
Headache	1.8%	0%	2.1%	0.1%

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Conclusions

・The extension of treatment with an adjuvant aromatase inhibitor (anastrozole) to 10 years resulted in significantly higher rates of disease-free survival and distant disease-free survival than those with no additional anastrozole.

Acknowledgements

- All the study participants, the families, all researchers, and staff at the CSPOR office in the AERAS trial.
- Special thanks to Ms.  niko Nomura of JCRSU for her support of the study.

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