N-SAS BC03　06年会報告

BC03研究代表者
相原智彦

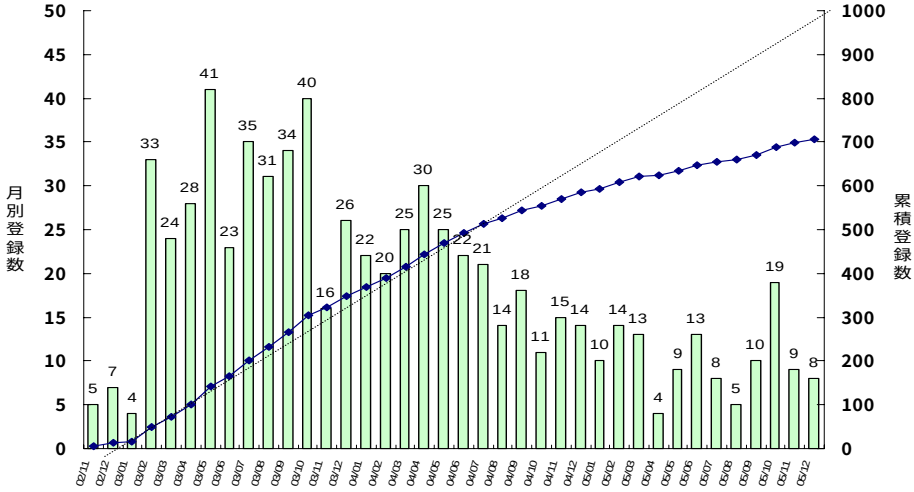
N-SAS BC03登録終了のご報告と御礼

N-SAS BC03は、2005年12月に706例をもって、登録終了しました

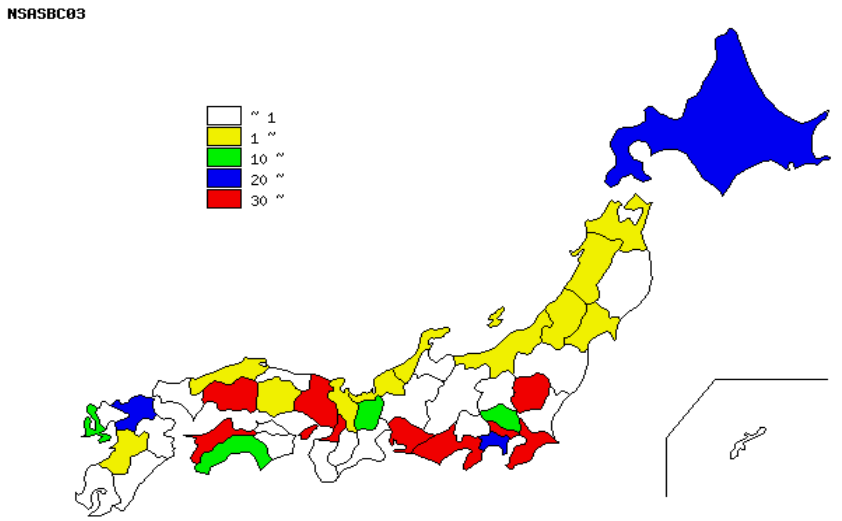
ご参加頂いた乳癌患者の皆様・研究者の皆様・関係者の皆様に御礼申し上げます

N-SAS BC03　登録状況

ＩＲＢ通過施設　１１０施設　　登録数　７０６症例



都道府県別登録状況



サンアントニオ乳癌シンポジウムでの発表

•Side effect profile of anastrozole compared with tamoxifen in Japanese women: findings from N-SAS BC03 Trial. *Aihara T, et al.*

•HR-QOL and psychological distress of breast cancer patients after surgery during phase Ⅲ randomized trial comparing further tamoxifen with switching to anastrozole after adjuvant tamoxifen for 1 to 4 years: N-SAS BC 03. *Ohsumi S, et al.*

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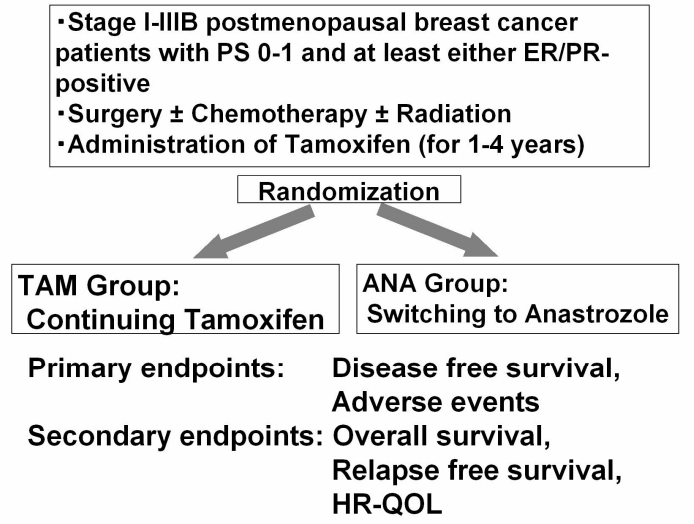
N-SAS BC03 Trial scheme



Primary endpoints: Disease free survival, Adverse events

Secondary endpoints: Overall survival, Relapse free survival, HR-QOL

Trial data

No. of patients	691
Recruitment period	Nov. 2002 – Dec. 2005
Median follow-up (range)	23 months (1–36 months)

The data from the 622 patients accrued by the end of April 2005 was analyzed in this paper.
The information as of Nov. 2005 is presented above.
Patient accrual will be finished on Dec. 2005.

Patient demographics

		TAM n=310	ANA n=312	Total n=622
Clinical stage	Ⅰ	132	127	259
	ⅡA	107	110	217
	ⅡB	50	53	103
	ⅢA	12	8	20
	ⅢB	9	14	23
Nodal status	0	184	181	365
	1～3	89	94	183
	4≦	37	37	74
HER2	Unknown	164	165	329
	0～2+	133	134	267
	3+	13	13	26
Tumor size	＜3cm	247	247	494
	3cm≦	63	65	128
ER/PR	ER(+) PR(+)	216	220	436
	ER(+) PR(-)	69	67	136
	ER(-) PR(+)	25	25	50
Type of surgery	Breast conserving	156	158	314
	Mastectomy	154	154	308
Duration of tamoxifen treatment	1.0-2.0 y	145	146	291
	2.0-4.0y	164	166	330
Age at randomization	59 y.o. ≦	154	156	310
	≧60 y.o.	156	156	312
Chemotherapy	Yes	147	146	293
	No	163	166	329

Methods

・The worst toxicity grade (NCI-CTC ver2.0) after randomization of 15 predefined adverse events were compared between ANA (n=277) and TAM (n=279).

・ Cochran-Mantel-Haenszel test was used. $p<0.05$ was considered as statistically significant.

Results

Adverse event	At baseline		After randomization		CMH statistical amount	p value
	A(n,[%]) n=277	T(n, [%]) n=279	A(n, [%]) n=277	T(n, [%]) n=279	(ANOVA)	
Hot flushes	78(28)	71(25)	106(38)	107(38)	2.43	0.12
Nausea	3(1.1)	4(1.4)	17(6.1)	13(4.7)	0.02	0.89
Appetite loss	3(1.1)	4(1.4)	8(2.9)	12(4.3)	0.04	0.84
Fatigue	33(12)	28(10)	70(25)	57(20)	0.00	0.99
Mood alteration	18(6.5)	12(4.3)	35(13)	23(8.3)	0.66	0.42
Headache	16(5.8)	16(5.8)	47(17)	35(13)	0.03	0.86
Arthralgia	37(13)	26(9.4)	105(38)	56(20)	0.28	0.60
White blood cell count	21(7.6)	23(8.3)	53(19)	47(17)	0.19	0.66
Liver dysfunction	29(10)	23(8.3)	79(29)	51(18)	0.02	0.90
Thrombosis	0	0	0	0	-	-
Vaginal bleeding	4(1.4)	5(1.8)	16(5.8)	12(4.3)	0.00	0.99
Vaginal discharge	50(18)	44(16)	64(23)	62(22)	3.47	0.06
Cardiovascular	2(0.72)	1(0.36)	3(1.1)	2(0.72)	0.98	0.32
Second malignancy	0	0	1(0.36)	2(0.72)	-	-
Contra-lateral breast cancer	0	0	0	1(0.36)	-	-

Results of other studies

	Hot flashes	Gynec. symptoms
•ARNO/ABCSG:	NS	NS
•ITA:	-	ANA>TAM
•IES:	NS	EXE>TAM

Results & Conclusion

- No significant difference was observed in any of the predefined adverse events, but marginally significant difference was observed in hot flushes and vaginal discharge in favor of anastrozole.

- Further follow-up will reveal the similarity and difference in the toxicity profile of aromatase inhibitors between Western and Asian population.