Ongoing Breast Cancer Clinical Trials in Korea

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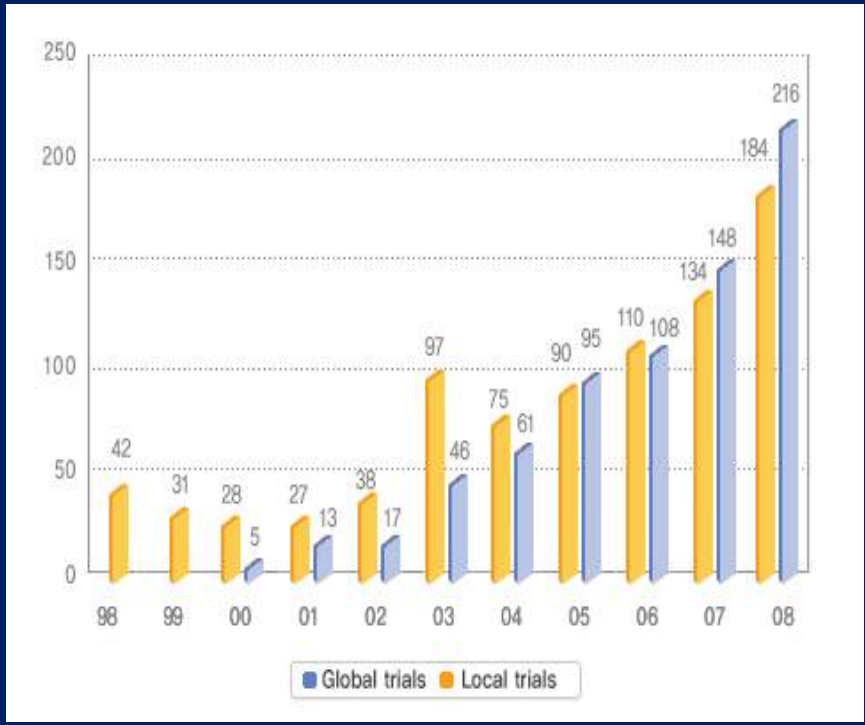
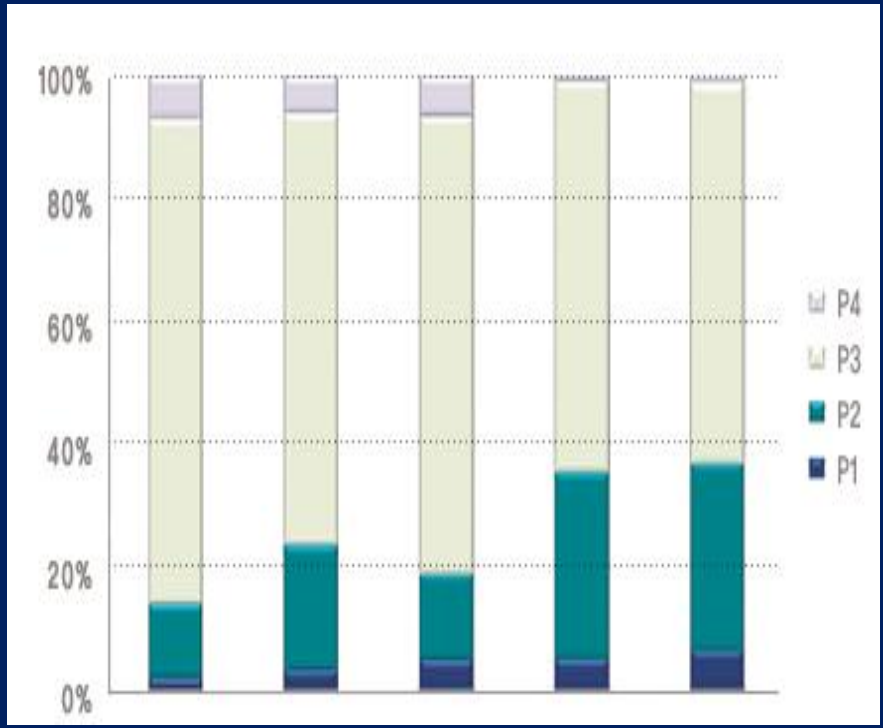
Clinical Trials in Korea



Global + Local Trials



2004 2005 2006 2007 2008

From KoNECT (Korea National Enterprise for Clinical Trials)

Two Beast Cancer Study Groups in Korea

1. Korean Breast Cancer Society (KBCS)

한국유방암학회
KOREAN BREAST CANCER SOCIETY

2. Korean Cancer Study Group (KCSG)
--- Breast Cancer Subcommitte

KCSG Korean Cancer Study Group 대한항암요법연구회

Ongoing Breast Cancer Clinical Trials in Korea

	Investigator-initiated Trials(Ongoing)	Investigator-initiated Trials(F/U)	Sponsor-initiated trials(Ongoing)	Sponsor-initiated trials(F/U)
Adjuvant trials	JBCRG-04 Letrozole QoL, BMD (postmenopausal) ASTRRA	Zometa Trial (Premenopausal)	TEACH ALTTO BETH BEATRICE	HERA BCIRG005 BCIRG006
Neoadjuvant trials		PGH study	Neo-Sphere Neo-ALTTO CA163-100	
Palliative trials	PG maintenance TS-1 + Oxaliplatin (TORCH) Bone Remodeling Marker Study		AVADO Docetaxel +/-TSU-68 Cleopatra SOFEA HKI272(3003) TRIO-012 Bosutinib(2206) EGF109275 EMILIA STRIDE BOLERO-1	EGF30001 EGF30008 CA163-046 CA163-048 B9E-US-S188 RPR10988 Lapatinib EAP RIBBON
	KOHBRA study			

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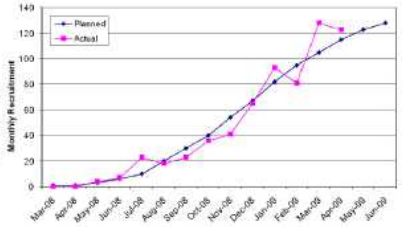
	KOHBRA study			

Highest Recruiting Sites in Global Clinical Trials

BETH

BETH Recruitment

31st March 2011 is the target date for the completion of the patient recruitment phase of the BETH Trial. Although the first patient was randomized in May 2008, one month later than expected, by the end of April 2009 a total of 642 patients had been randomized, 13 more patients than planned. Every month, newly initiated sites are adding momentum to the accelerating recruitment rate: as of the 1st May, 660 sites were activated in 25 countries around the world.



The Top 10 (1st May 2009)

1. **Dr. Young-Hyuck Im,** Republic of Korea, site 6301, CIRG, 40 patients
2. **Dr. Sung-Bae Kim,** Republic of Korea, site 6302, CIRG, 19 patients
3. **Dr. Tadeusz Pienkowski,** Poland, site 2500, CIRG, 15 patients
4. **Prof Jonathon Polikoff,** USA, site 946, NSABP, 11 patients
5. **Dr Lou Fehrenbacher,** USA, site 290, NSABP, 11 patients
6. **Dr Patrick Flynn,** USA, site 936, NSABP, 11 patients
7. **Prof. Wolfgang Eiermann,** Germany, site 1005, CIRGF, 10 patients
8. **Dr Alexander Paterson,** Canada, site 104TB, NSABP, 9 patients
9. **Dr John Zapas,** USA, site 446, NSABP, 9 patients
10. **Dr James Atkins,** USA, site 928, NSABP, 8 patients

PLANNED BETH INVESTIGATOR MEETINGS
Europe: 18-19 June 2009 (Rome)
China: Location & dates to be confirmed

Trial Status (1st May 2009)

Country	Activated Sites	Randomized Patients
Australia	5	7
Austria	10	14
Belgium	4	14
Bosnia & Herzegowina	1	6
Canada	21	61
Estonia	1	0
France	10	10
Germany	27	47
Greece	1	0
Ireland	7	6
Italy	9	6
Republic of Korea	5	70
Latvia	1	0
Mexico	2	0
Peru	2	0
Philippines	1	1
Poland	4	21
Romania	2	3
Serbia	3	0
Slovenia	1	0
South Africa	3	1
Spain	34	40
Sweden	2	5
Thailand	2	0
U.S.A.	502	338
TOTAL	660	650

ALTTO

Issue 4
May 2009

BIG 2-06 / N063D / EGF106708

ALTTO
Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Trial

Additional Translational Research in ALTTO - Update

ALTTO Additional Translational Research was officially launched in March 2009. To date, only 67 centres from countries around Europe have indicated an interest in participating in this initiative. Unfortunately, the number of actual participants is less than expected as many sites ultimately decided not to take part in the translational research component mainly due to the closure of Design 1 in the ALTTO study.

Currently, 36 of the 67 centres that indicated an interest have been supplied with the materials to perform the planned sampling. The remaining 31 centres currently do not have approval for translational research on their informed consent forms (ICF). Once this approval is granted they will also be supplied the necessary materials.

As a reminder, ALTTO's Additional Translational Research involves sampling, at different time points, of frozen tumour tissue, serum for proteomics research and blood for circulating tumour cells (CTC) analysis.

Until now, the collection of samples has been far from optimal and the support of Investigators is crucial in order for us to answer essential scientific questions. One of the most challenging issues in the ALTTO study is identifying markers that can accurately predict sensitivity/resistance to anti-HER2 drugs. Obtaining these results will facilitate the individualisation of patient treatment and thus avoid administering toxic treatments to breast cancer patients for whom it is unnecessary.

INSIDE THIS ISSUE:

The translational research within the ALTTO study provides an excellent opportunity to prospectively examine the prognostic and predictive role of CTCs in early breast cancer patients, as well as to perform serum proteomics. Both these areas have the potential to provide new tools for tailoring therapy in the breast cancer setting.

We would like to encourage the sites already participating in the ALTTO Additional Translational Research to continue supporting the initiative by collecting as many samples as possible. Procedures for collection, storage and/or shipment should be carefully followed to ensure high quality sampling, which is critical for the success of the whole translational research component. Procedures can be found on the www.alttotrials.com website under the "Investigator/ALTTO trial documentation" section.

We would also like to invite sites that are not currently participating in the ALTTO Additional Translational Research to join this ambitious undertaking. If you are interested, it is still possible to apply to participate and we would be happy to provide you with the additional information. Therefore, please do not hesitate to contact the ALTTO Translational Research Coordinator at Jules Bordet Institute, Dr Marion Maetens (marion.maetens@bordet.be) for any further assistance and information.

Special Thanks

The ALTTO Study Team would like to give special thanks to Dr Young Hyuck Im at the Samsung Medical Centre in South Korea for his enthusiasm and dedication to the ALTTO study. Dr Im and his site staff have recruited more patients onto the study than any other site and he has shown great care for both his patients and the collection of the study data. In total 78 patients have been recruited since the starting recruitment in January 2008.

BEATRICE

BEATRICE Newsletter

An international multi-centre open-label 2-arm phase III trial of adjuvant bevacizumab in "triple negative" breast cancer

beatrice

Message from our highest recruiting site

Dear study group, colleagues and friends,

I'm pleased to have been asked to write an article for the 4th BEATRICE newsletter. Now that the study is well underway in most of the sites participating in this trial, it is a good moment to share some of the experience that we as a team here in the "Samsung Medical Centre (SMC)" in Korea have built up over time.

The BEATRICE study is surely a very challenging study in many respects; however our interest was primarily driven by the academic nature of the trial. When discussing this study with my staff in the hospital it became clear very quickly that not only does this study seek to address important scientific questions for a very poor patient population, in addition, it is extremely important to align the efforts between the various disciplines within the hospital to ensure successful completion of the trial on all aspects.

Our institution is a Comprehensive Cancer Centre and we have many breast cancer patients' resources. Actually over 1,000 newly diagnosed breast cancer patients have received breast cancer operation in our institution since January 2008. In our site, we have currently enrolled 43 patients in the trial and we are looking forward to enrol more patients. The recruitment end for this study is currently planned for the fourth quarter of next year and given that at this stage already more than 817 patients have been recruited, I am confident that the entire BEATRICE study group will be able to recruit the required sample size in time.

Furthermore the team is also working hard to enter the study data in time on the database. The study team is now fully equipped with 3 active medical oncologists, clinical fellows, 2 BEATRICE study coordinators and outpatients nurses who enthusiastically devote themselves to this trial. Knowing this is a large task, but the most important aspect is enthusiasm and devotion of investigators and study coordinators for the study. Obviously it must be noted that the use of the web based electronic data capture system is very helpful for the team.

It is important to raise awareness about biologic and clinical significance of triple negative breast cancers for this subgroup of patients so these patients can become motivated and empowered to participate in this study. On behalf of the SMC study team, I'd like to thank our patients for their willingness to participate in this important study and hence contribute important scientific information regarding therapy in this small patient population who are in need for better medical treatment. We feel privileged to be part of this very important scientific undertaking, which could be a major step within the field of triple negative adjuvant breast cancer.

Young-Hyuck Im, MD, PhD

Principal Investigator for the Samsung Medical Centre (SMC) in Korea

Photo (from Left to Right)
PI: Dr Young-Hyuck IM / SC: Ms Woo-Jin PARK/ Sub-I: Dr Jin-Seok AHN/ SC: Eun Jee LEE (She will be a SC for Beatrice study soon) / Lead Nurse: Young Mee HAN / Sub-I: Dr Yeon Hee PARK

Ongoing Breast Cancer Clinical Trials in Korea

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	KOHBRA study			

JBCRG-04

Japan Breast Cancer Research Group(JBCRG)

Korean Breast Cancer Society (KBCS)

Korean Cancer Study Group (KCSG)

Investigation of a capecitabine as a Postoperative adjuvant chemotherapy in breast cancer patient who were pathologically confirmed to have residual tumors after preoperative chemotherapy: Phase III comparative study

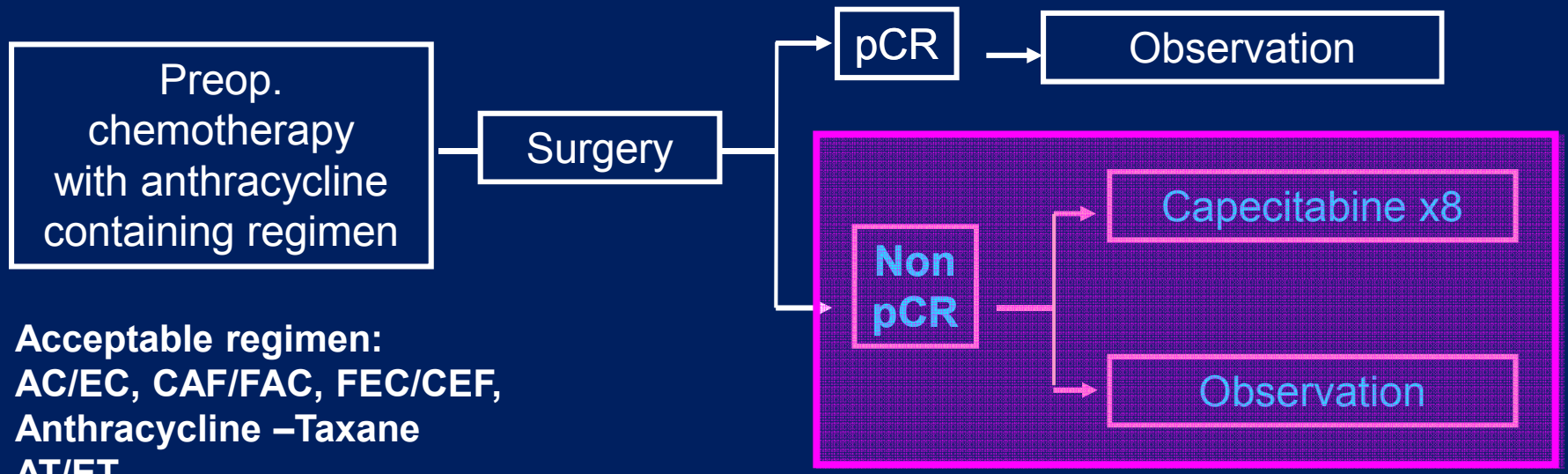
Background

- The high pCR rates are currently achieved by neoadjuvant chemotherapy involving anthracycline and taxanes.
- However, there remain uncertainties about the necessity for postoperative systemic chemotherapy in patients with whom pCR is not demonstrated.

JBCRG-04

Study Design

Study Design : phase III, randomized, multicenter trial (Korea & Japan)



Acceptable regimen:
AC/EC, CAF/FAC, FEC/CEF,
Anthracycline –Taxane
AT/ET

Adjuvant hormonal therapy if HR(+)

Total No. of pts: 900 (450 per group)
Korea 300 /Japan 600

Primary end point: DFS

Ongoing Breast Cancer Clinical Trials in Korea

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	KOHBRA study			

한국유방암학회
KOREAN BREAST CANCER SOCIETY

KBCS-03

Assessment of Quality of Life, BMD, and Safety profile in postmenopausal patients with Letrozole (*Femara*®) as an early adjuvant treatment

Objectives

Primary end point

To compare the overall QoL (Quality of Life) using Trial Outcome Index (TOI) of FACT-B questionnaire for 2 years from baseline.

(TOI is the sum of the scores from the physical and functional well-being and the breast cancer subscales.)

Objectives *(cont'd)*

Secondary end point

1) To assess incidence of adverse events (including cardiovascular, cerebrovascular, and endocrine, musculoskeletal) in Korean postmenopausal breast cancer patients in early adjuvant setting

2) To assess the effect of letrozole(*Femara*®) on BMD in early adjuvant setting.

3) To assess the effect of letrozole(*Femara*®) on total cholesterol in early adjuvant setting.

Protocol No: KBCS- 03

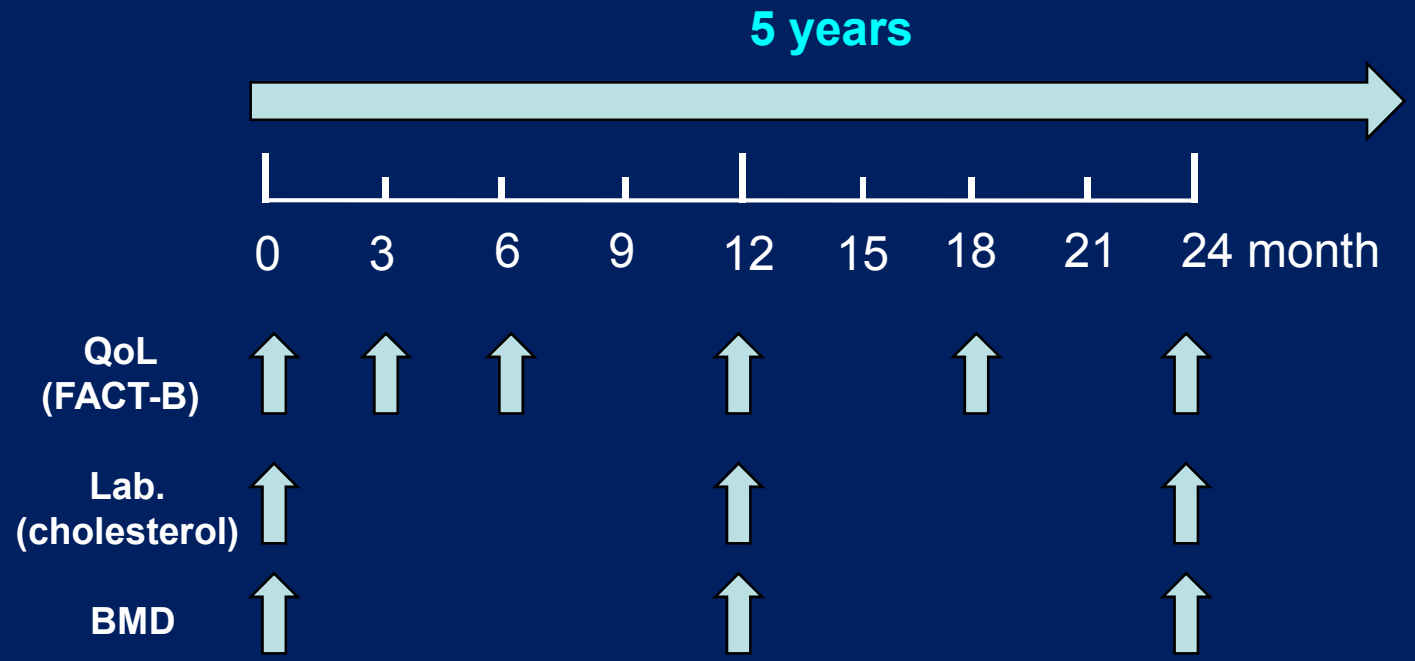
Letrozole QoL study

Study Design : phase II, multicenter trial

Study Period : 2007.08 - 2011.12

Postmenopausal women who received curative surgery

ER &/or PR(+)



Primary End point: Quality of Life
Secondary End Points: Cholesterol, BMD

Target No: 900
Enrolled pts:

Ongoing Breast Cancer Clinical Trials in Korea

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	KOHBRA study			

한국유방암학회
KOREAN BREAST CANCER SOCIETY

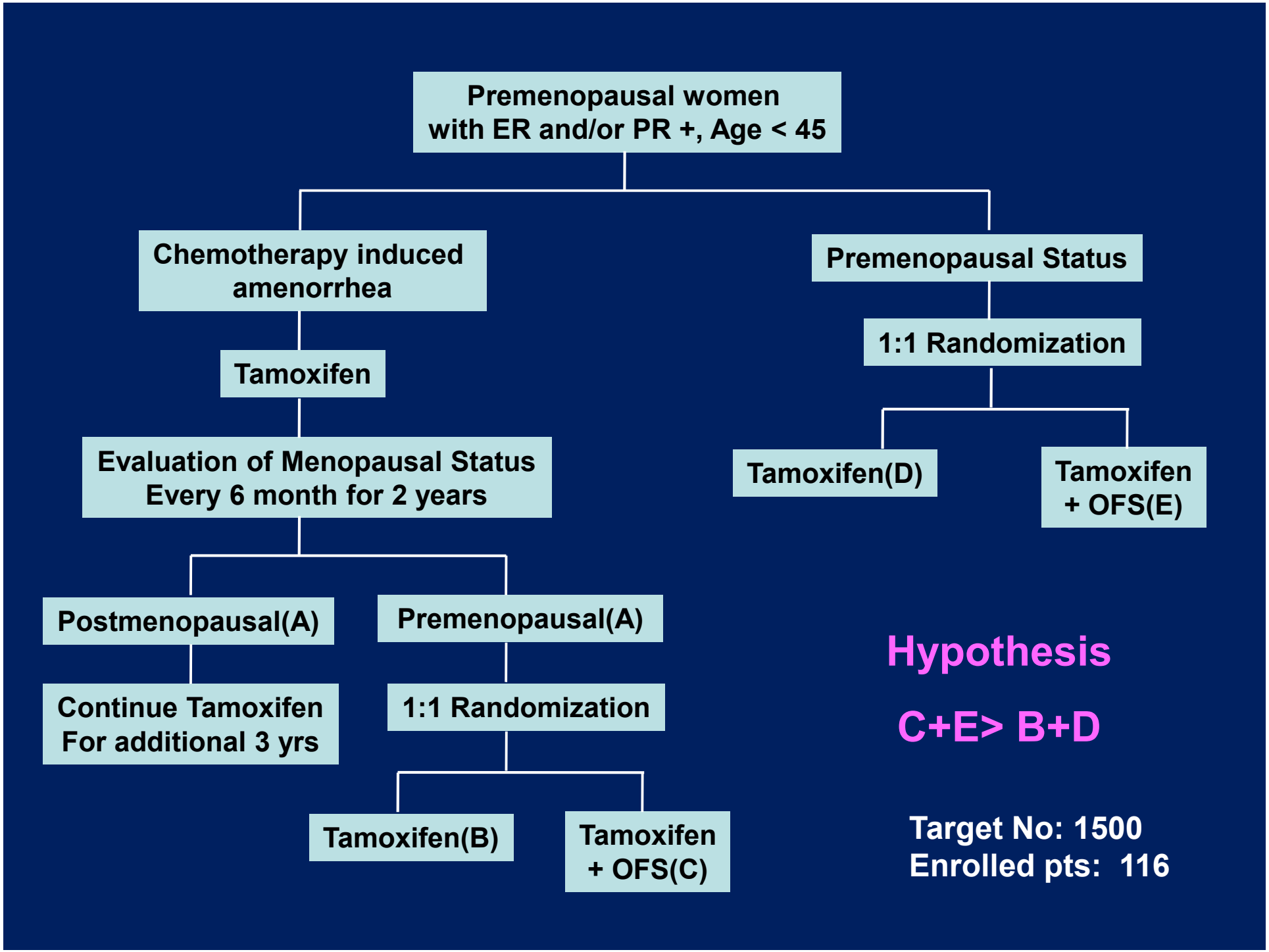
A randomised phase III study for evaluating the role of the Addition of ovarian Suppression (OFS) to Tamoxifen in young women (≤45 years) with hormone-sensitive breast cancer who Remain in premenopause or Regain menstruation After chemotherapy (ASTRRA)

ASTRRA (Primary Objective)

- To compare 5-year disease free survival rate (DFS rate) between the hormone receptor positive breast cancer patients who were added Goserelin to Tamoxifen for ovarian function suppression including delayed ovarian function supression until 2 years after adjuvant cytotoxic chemotherapy and the hormone receptor positive breast cancer patients who were treated with Tamoxifen alone in premenopausal status

Secondary Objectives

- To compare overall Survival (OS)
- To evaluate the prognostic impact of CIA
- To determine the tolerability of Tamoxifen with or without concomitant Zoladex


Premenopausal women with ER and/or PR +, Age < 45
Chemotherapy induced amenorrhea
Tamoxifen
Evaluation of Menopausal Status Every 6 month for 2 years
Postmenopausal(A)
Continue Tamoxifen For additional 3 yrs
Premenopausal(A)
1:1 Randomization
Tamoxifen(B)
Tamoxifen + OFS(C)
Premenopausal Status
1:1 Randomization
Tamoxifen(D)
Tamoxifen + OFS(E)
Hypothesis
C+E> B+D
Target No: 1500
Enrolled pts: 116

Ongoing Breast Cancer Clinical Trials in Korea

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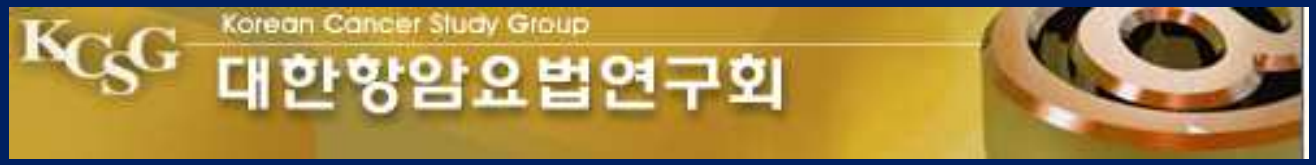
	KOHBRA study			



Protocol No: KCSG - BR06 - 01

A randomized, double-blind, placebo-controlled trial of intravenous zoledronic acid for the prevention of bone loss in premenopausal women treated with adjuvant chemotherapy for primary breast cancer

Background

- In a majority of premenopausal patients, adjuvant chemotherapy causes early menopause due to premature ovarian failure and rapid bone loss which may increase the risk of osteoporosis later in life.

- Therefore, prevention of bone loss in young breast cancer patients with treatment-induced early menopause is an important challenge

Study Objectives

Primary end point :

to determine the effectiveness of zoledronic acid in preventing bone loss in premenopausal patients over age 40 years who receive adjuvant chemotherapy

Secondary end points

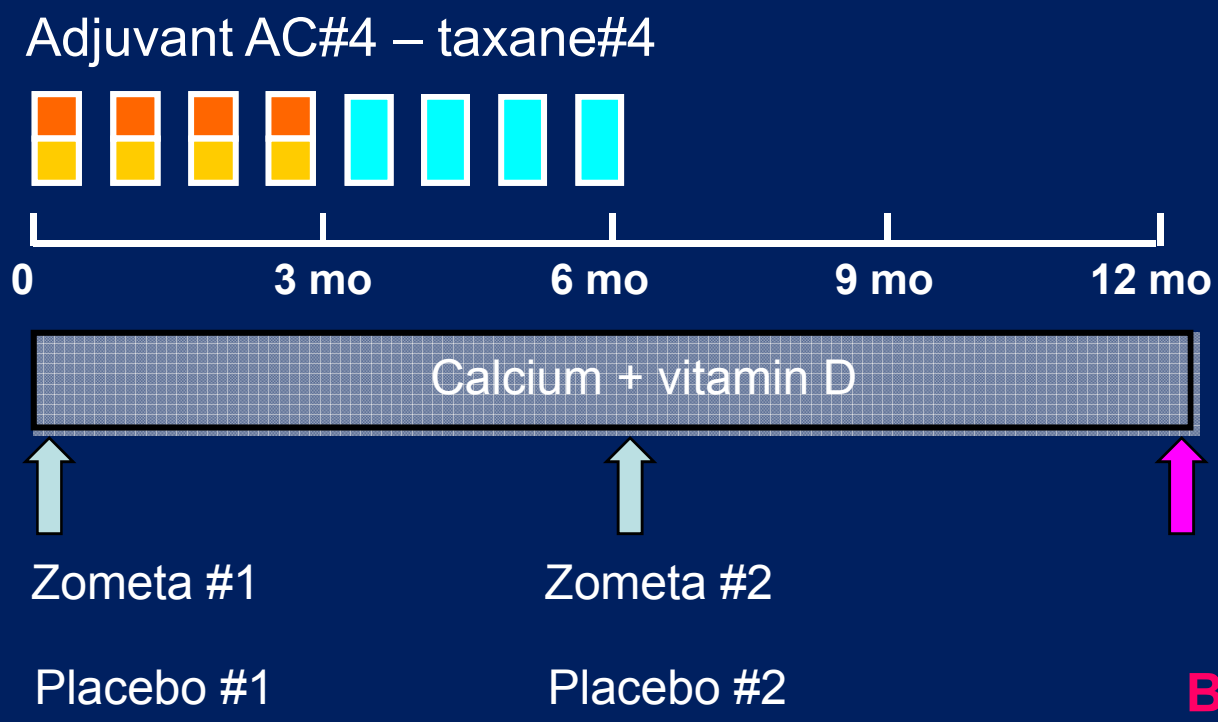
1) change in hip BMD
2) incidence of clinical fracture
3) the effects of zoledronic acid on markers of bone turnover
4) time to bone metastases as first recurrence & disease-free survival (DFS)

Protocol No: KCSG - BR06 - 01

Study Design

Study Design : phase III, randomized, multicenter trial

Study Period : 2007.05 – 2008.12



Age > 40
Premenopausal
Curative surgery

Primary End point: percent change of lumbar spine BMD at 1 year

Target No: 120(60 in each arm)
Enrolled pts: 120/120 (100%)

Ongoing Breast Cancer Clinical Trials in Korea

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Adjuvant trials	JBCRG-04 Letrozole QoL, BMD (postmenopausal) ASTRRA	Zometa Trial (Premenopausal)	TEACH ALTTO BETH BEATRICE	HERA BCIRG005 BCIRG006
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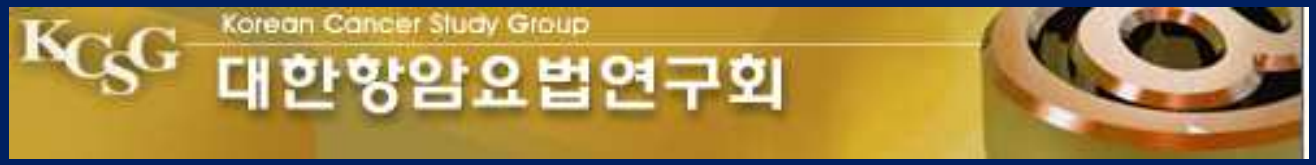
	KOHBRA study			



Protocol No: KCSG - BR07 - 01

Phase II Study of Primary Chemotherapy with Paclitaxel, Gemcitabine, and Trastuzumab in Patients with HER2 (+) Operable Breast Cancer

Background

- Paclitaxel plus gemcitabine combination showed overall survival benefit compared to paclitaxel alone in patients with metastatic breast cancer
- Buzdar *et al.* showed that adding trastuzumab significantly increased pCR from 25% to 66.7% in sequential paclitaxel and FEC chemotherapy in combination with trastuzumab arm in preoperative setting for HER2 positive disease.

Study Objectives

Primary Objective

- To evaluate the pathologic CR rate to preoperative administration of paclitaxel plus gemcitabine in combination with trastuzumab (Herceptin®) (PGH)

Secondary objectives

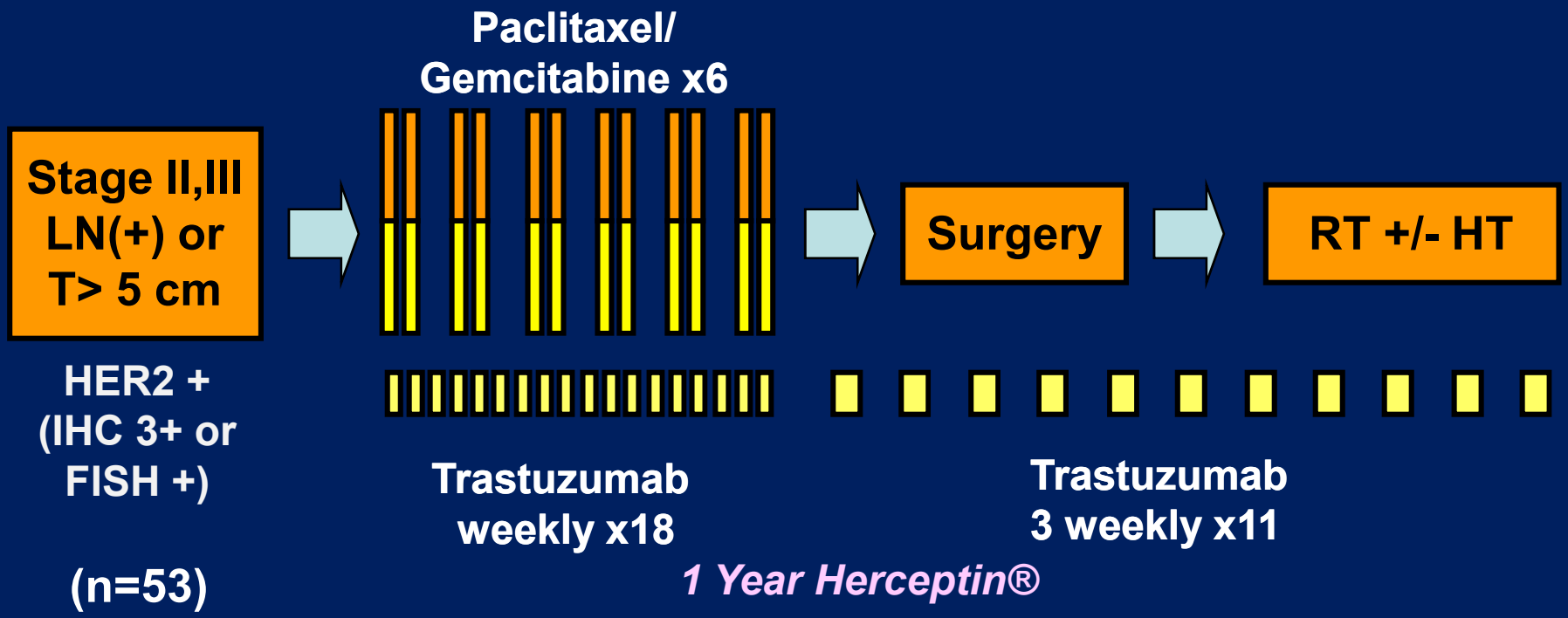
- To assess breast conserving rate after preoperative chemotherapy
- To evaluate clinical response rate, disease free survival (DFS), and overall survival (OS)
- To assess the toxicity profiles of paclitaxel plus gemcitabine in combination with trastuzumab

Protocol No: KCSG - BR07 - 01

PGH Study

Study Design : phase II, multicenter trial

Study Period : 2007.05 – 2008.12



Primary End point: Pathologic CR

Target No: 53
Enrolled pts: 53/53 (100%)

Ongoing Breast Cancer Clinical Trials in Korea

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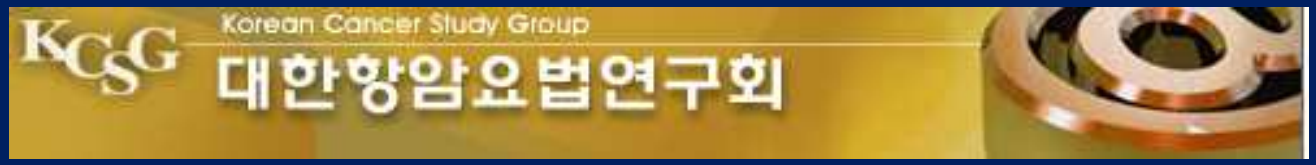
	KOHBRA study			

Protocol No: KCSG - BR07 - 02



A Phase III, Multicenter, Randomized Trial of Maintenance Versus Observation After Achieving Clinical Response in Patients With Metastatic or Recurrent Breast Cancer Who Received 6 Cycles of Gemcitabine Plus Paclitaxel(GP) as First-line Chemotherapy

Background

- The duration of chemotherapy in patients responding or stable disease remains controversial, since quality of life is not usually adversely affected and may even be improved in many patients receiving cytotoxic chemotherapy.
- In pre-taxane era, randomized studies suggest that maintenance chemotherapy is associated with superior time to progression but no survival gain.
- However, these randomized trials did not incorporate taxane-based chemotherapeutic regimens, the new standard of care in metastatic breast cancer patients these days.

Study Objectives

Primary objective:

To demonstrate that the maintenance chemotherapy with Gemcitabine plus Paclitaxel combination in responders (CR/PR/SD) group is superior to the observation group in terms of **Progression Free Survival** in metastatic breast cancer patients.

Secondary End Points;

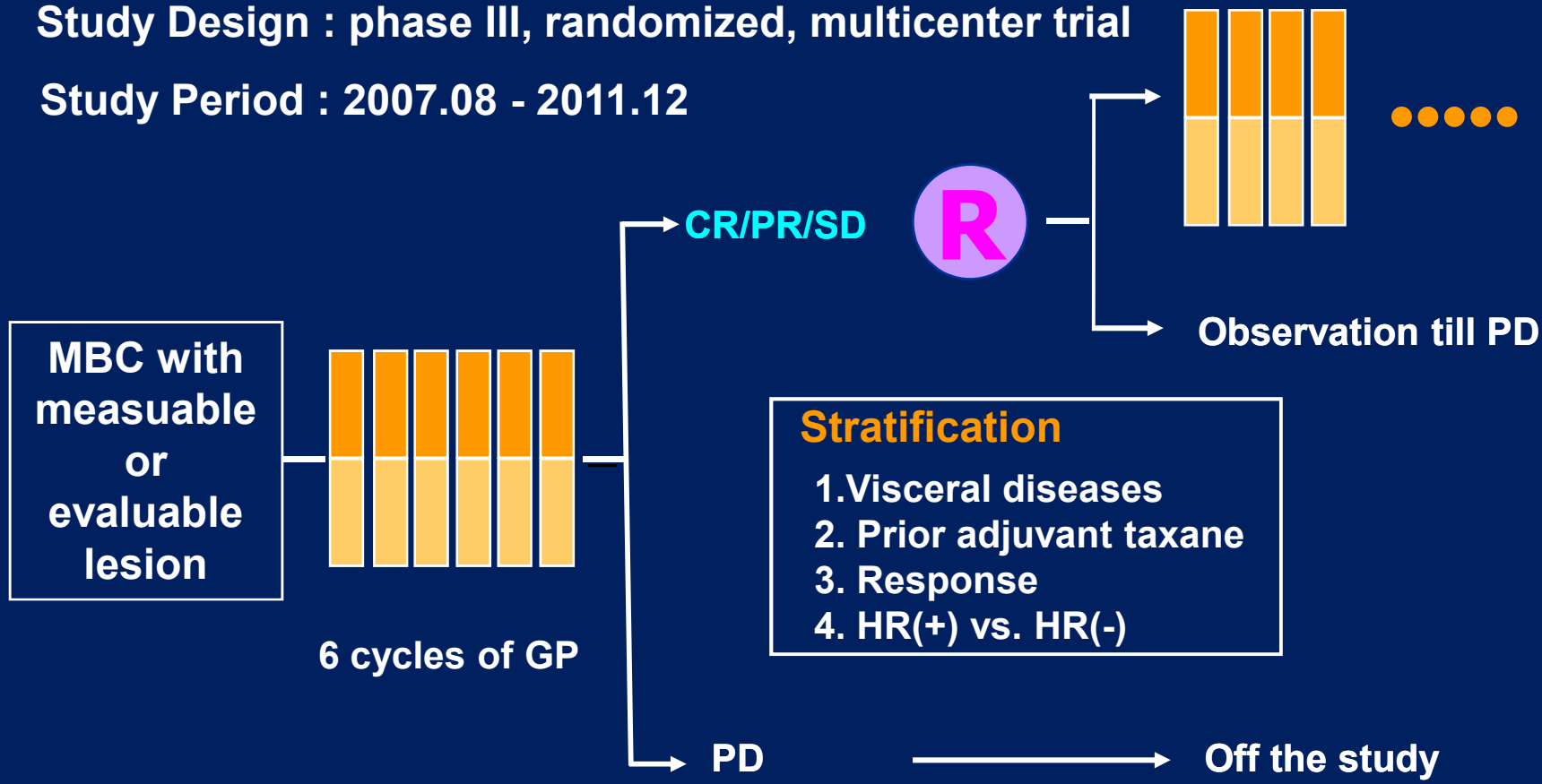
1) overall survival
2) quality of life
3) toxicity
4) duration of response

Protocol No: KCSG - BR07 - 02

Maintenance Study

Study Design : phase III, randomized, multicenter trial

Study Period : 2007.08 - 2011.12



Primary End point: Progression Free Survival

Secondary End Points: Overall Survival, Toxicity

Target No: 326

Enrolled pts: 224/326 (69%)

Ongoing Breast Cancer Clinical Trials in Korea

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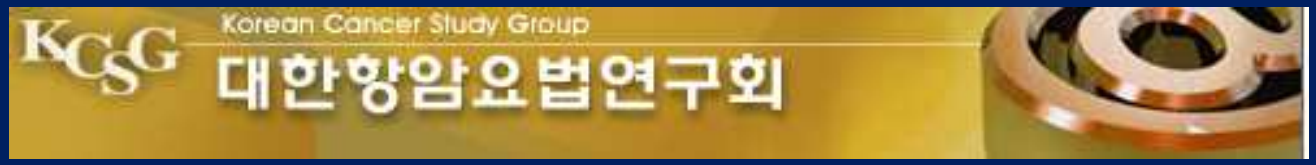
	KOHBRA study			

Protocol No: KCSG - BR07 - 03



Phase II trial of TS-1 in combination with oxaliplatin (SOX) in patients with recurrent or metastatic breast cancer (MBC) previously treated with or resistant to an anthracycline and taxane chemotherapy [TORCH]

Background

- Capecitabine(+/- ixabepilone): 3rd line FDA approved chemotherapeutic regimen (anthracycline, taxane refractory BC)
- 5-FU/LV + oxaliplatin in anthracycline and taxane refractory breast cancer
  : ORR 27-34%, TTP: 4-5 months
- 5-FU and oxaliplatin: synergism
- TS-1 in taxane refractory breast cancer
  : R.R.: 21.8% and tolerable

Study Objectives

Primary endpoint

To evaluate the response rates of S-1 and oxaliplatin combination chemotherapy in patients with metastatic or recurrent breast cancer who were refractory to anthracycline and taxanes

Secondary endpoint

time-to-progression
response duration
overall survival
Toxicit
Predictive factor analysis (collateral study)

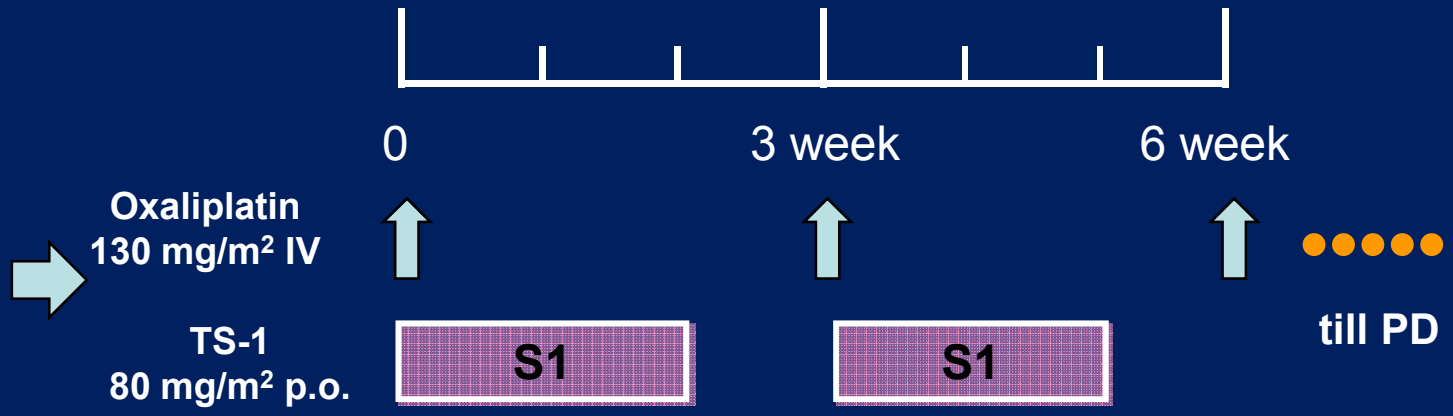
Protocol No: KCSG - BR07 - 03

TORCH Study

Study Design : phase II, multicenter trial

Study Period : 2007.10 - 2010.08

Recurrent or MBC patients who are refractory to anthracycline and taxanes



Repeat every 3 weeks

Primary End point: Response Rate
Secondary End Points: PFS, Toxicity,

Target No: 86
Enrolled pts: 83/86 (97%)

Ongoing Breast Cancer Clinical Trials in Korea

	Investigator-initiated Trials(Ongoing)	Investigator-initiated Trials(F/U)	Sponsor-initiated trials(Ongoing)	Sponsor-initiated trials(F/U)
Adjuvant trials	JBCRG-04 Letrozole QoL, BMD (postmenopausal) ASTRRA	Zometa Trial (Premenopausal)	TEACH ALTTO BETH BEATRICE	HERA BCIRG005 BCIRG006
Neoadjuvant trials		PGH study	Neo-Sphere Neo-ALTTO CA163-100	
Palliative trials	PG maintenance TS-1 + Oxaliplatin (TORCH) **Bone Remodeling Marker Study**		AVADO Docetaxel +/-TSU-68 Cleopatra SOFEA HKI272(3003) TRIO-012 Bosutinib(2206) EGF109275 EMILIA STRIDE BOLERO-1	EGF30001 EGF30008 CA163-046 CA163-048 B9E-US-S188 RPR10988 Lapatinib EAP RIBBON
	KOHBRA study			

Protocol No: KBCS- 04

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A phase IV, multi-center, open label, single arm clinical trial to evaluate the relationship of bone remodeling markers for skeletal complications in metastatic breast cancer patients

Study Objectives

Primary objective

to determine the prognostic role of bone turnover markers in advanced beast cancer patients with bone metastases receiving zoledronic acid in Korean population

Secondary objectives

- changes in bone turnover markers
- the incidence of SRE
- time to SRE
- time to bone metastases progression
- overall survival
- the incidence of each adverse event including osteonecrosis

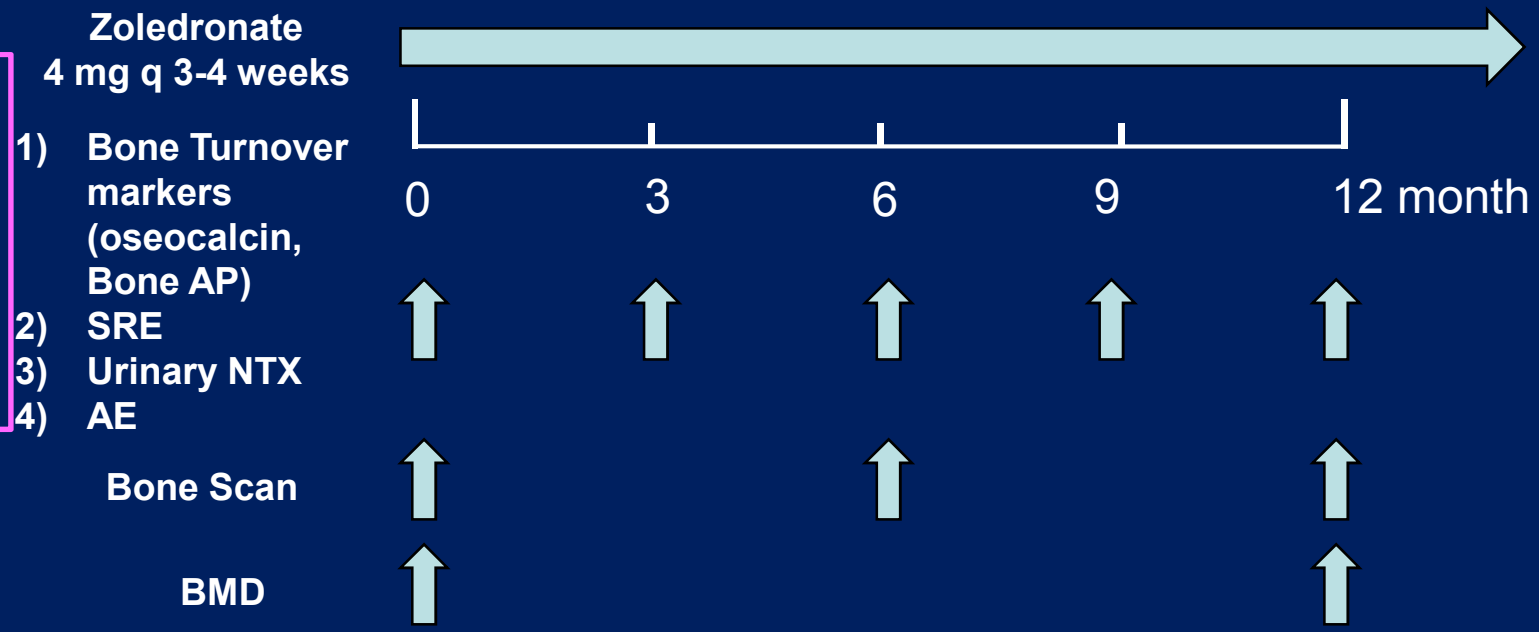
Protocol No: KBCS- 04

Bone Remodeling Marker Study

Study Design : phase IV, multicenter, open-label trial

Study Period : 2007.02 - 2010.12

Advanced breast cancer with bone metastases



Primary End point: Bone turnover markers
Secondary End Points: SRE, time to BM progression OS, AE including ONJ

Target No: 237
Enrolled pts: 116

Ongoing Breast Cancer Clinical Trials in Korea

	Investigator-initiated Trials(Ongoing)	Investigator-initiated Trials(F/U)	Sponsor-initiated trials(Ongoing)	Sponsor-initiated trials(F/U)
Adjuvant trials	JBCRG-04 Letrozole QoL, BMD (postmenopausal) ASTRRA	Zometa Trial (Premenopausal)	TEACH ALTTO BETH BEATRICE	HERA BCIRG005 BCIRG006
Neoadjuvant trials		PGH study	Neo-Sphere Neo-ALTTO CA163-100	
Palliative trials	PG maintenance TS-1 + Oxaliplatin (TORCH) Bone Remodeling Marker Study		AVADO Docetaxel +/-TSU-68 Cleopatra SOFEA HKI272(3003) TRIO-012 Bosutinib(2206) EGF109275 EMILIA STRIDE BOLERO-1	EGF30001 EGF30008 CA163-046 CA163-048 B9E-US-S188 RPR10988 Lapatinib EAP RIBBON
	KOHBRA study			

KBCS-04

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KOREAN BREAST CANCER SOCIETY

Korean Hereditary Breast Cancer Study [KOHBRA Study]

KOHBRA (KBCS-04)

- Part 1: Multi-institutional Cohort Study on the Identification of Candidate Genes and Prognosis of Korean Hereditary Breast Cancer
- Part 2: Multi-institutional Cohort Study on Cancer Risk Estimates from Korean BRCA Mutation Carriers
- Part 3: Korean Hereditary Breast Cancer Surveillance and Intervention Study
- Part 4: Development of Genetic Counseling Education Program for Hereditary Breast Cancer

Competitive Components for Clinical Trial in Korea

- High volume hospitals with excellent facilities
- Many talented and enthusiastic investigators who have a plenty of global trial experiences
- Well organized clinical trial centers in each hospital
- Relatively rapid recruitment rate (many cases in 1 center)
- Relatively low cost (?) in clinical trial
- High market potential for pharma industry

The Hub for Global Clinical Trials

Thank You
for Your Attention !!!