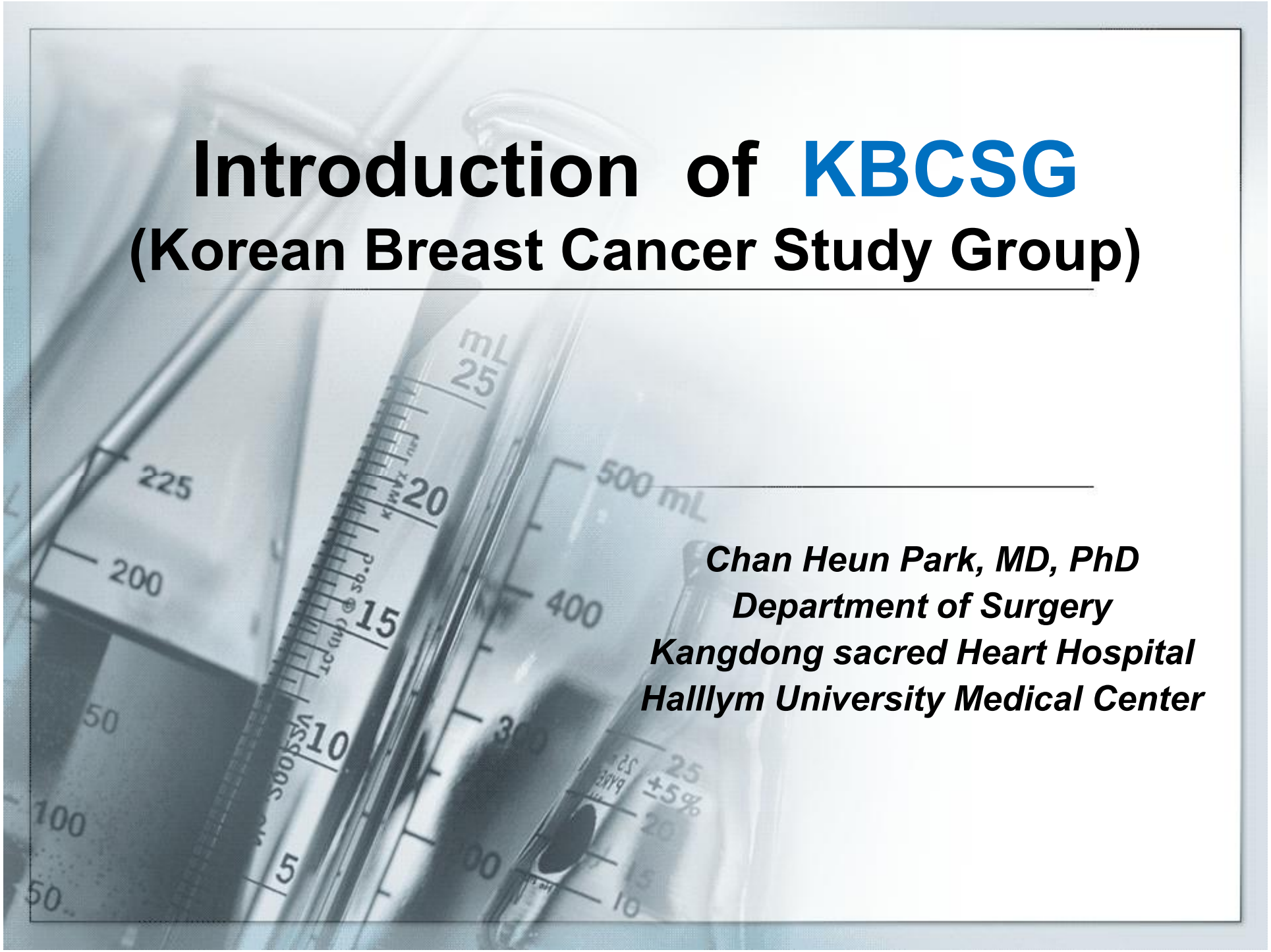
Introduction of KBCSG
(Korean Breast Cancer Study Group)



Chan Heun Park, MD, PhD
Department of Surgery
Kangdong sacred Heart Hospital
Halllym University Medical Center

Objectives of KBCSG

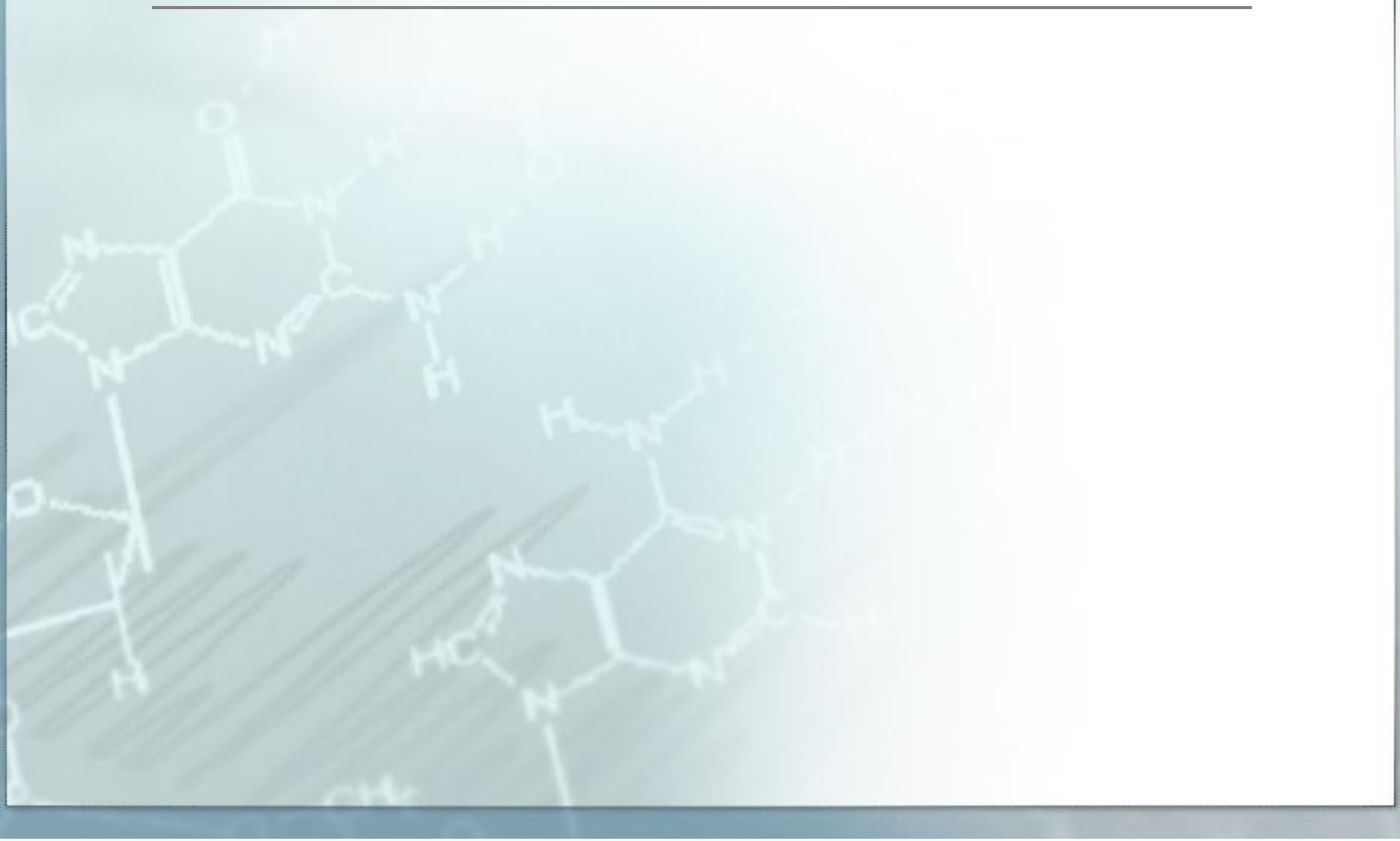
- Planning, implementation and coordination the clinical and translational research in Korea for active coping with breast cancer and contribution for the breast cancer patients to improve the quality of life

History

- **2008.11.15 :**
  Organization Meeting &
  1st KBCSG symposium

- **2009. 5.23 :**
  2nd KBCSG workshop & symposium

Structure of KBCSG



Ongoing trials

1. 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 **(KBCSG 001)**
2. Assessment of Quality of Life, BMD, and Safety profile on **postmenopausal patients with Letrozole**(Femara®) as an early adjuvant treatment **(KBCSG 002)**
3. KOHBRA (**Korean Hereditary Breast Cancer Study**, **KBCSG 003**)
4. Investigation of a **capecitabine** as a postoperative adjuvant chemotherap y in breast cancer patients who were pathologically confirmed to have **re sidual tumors after preoperative chemotherapy**: Phase-III comparativ e study
5. **Genexol PM** Phase III trial **(KBCSG 004)**
6. **ASTTRA (KBCSG 005)**

Evaluate the Relationship of Bone Remodeling Markers for Skeletal Complications in Metastatic Breast Cancer Patients (KBCSG 001)

- **Purpose**

  to evaluate whether bone marker can provide the valuable predictor of skeletal complications and whether regular assessing of NTX(N-telopeptide of type I collagen) and osteocalcin can be useful in advanced breast cancer patients with bone metastasis receiving zoledronic acid.

- **Condition: Metastatic Breast Cancer**
- **Intervention: Drug: zoledronic acid**
- **Phase: Phase IV**

- **Study Type:InterventionalStudy**
- **Design: Diagnostic, Open Label, Single Group Assignment, Safety/Efficacy Study**
- **Official Title: 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**

Treatment & Assessments

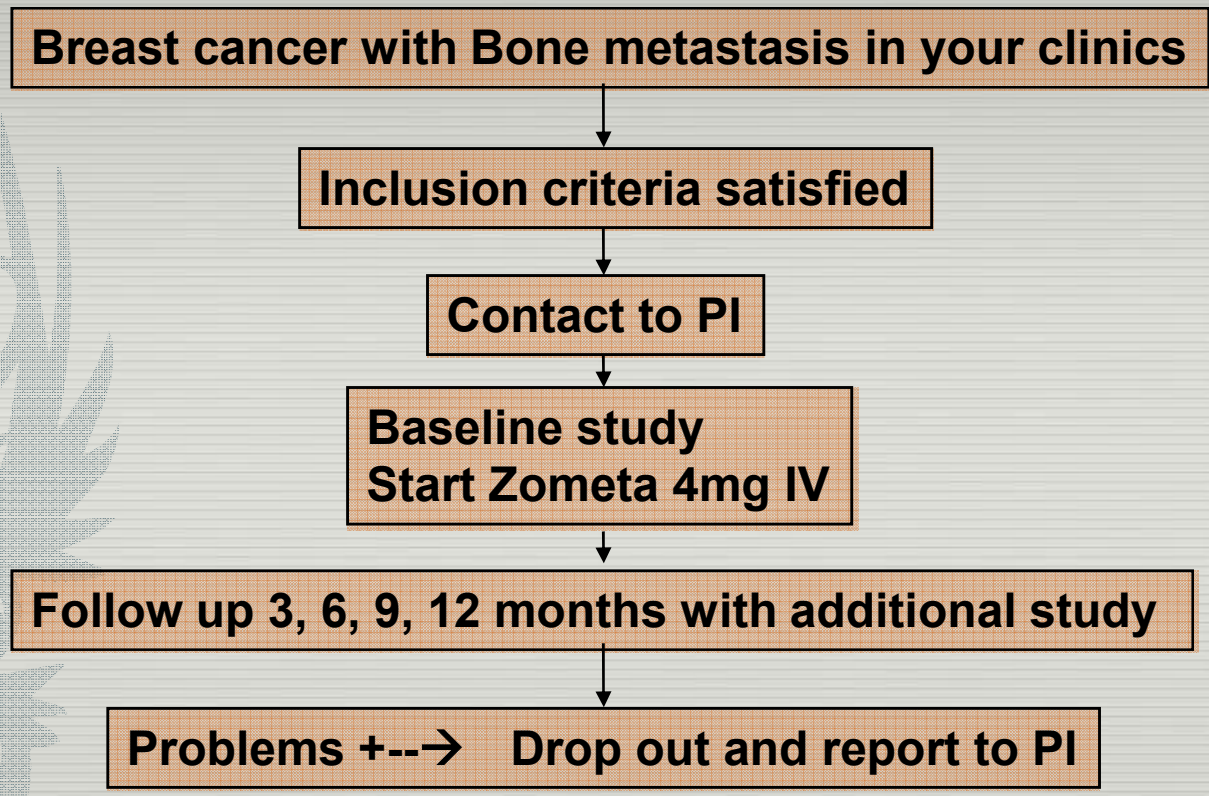
Treatment

Zometa 4mg IV q 3 or 4 weeks

Assessment

- Skeletal-related symptom
- Urine and blood sample for NTx, Bone alkaline phosphatase and osteocalcin
- Bone scan q 6 months
- Bone densitometry q 12 months

Algorithm


Breast cancer with Bone metastasis in your clinics
Inclusion criteria satisfied
Contact to PI
Baseline study
Start Zometa 4mg IV
Follow up 3, 6, 9, 12 months with additional study
Problems +--→ Drop out and report to PI

Study Design

Visit number	0	1	2	3	4
Time of Visit	day 1	Month 3	Month 6	Month 9	Month 12
Inclusion/Exclusion criteria	O				
Information & Informed consent	O				
Physical examination	O				O
Skeletal related events	O	O	O	O	O
Osteocalcin, Bone alkaline phosphatase	O	O	O	O	O
Urinary NTx	O	O	O	O	O
Bone scan	O		O		O
BMD	O				O
Adverse events	O	O	O	O	O
Concomitant medication	O	O	O	O	O

Assessment of Quality of Life, Bone Density and Safety in Postmenopausal Breast Cancer Patients With Letrozole Therapy (KBCSG 002)

- **Purpose**

  To compare the overall QoL (Quality of Life) using Trial Outcome index (TOI) of FACT-B questionnaire for 3 years from baseline.

- **Condition; Breast Cancer**
- **Phase; Phase IV**

- **Study Type: Observational Study**
- **Design: Cohort, Prospective**
- **Official Title: Assessment of Quality of Life, Bone Density and Safety in Postmenopausal Breast Cancer Patients With Letrozole (Femara) as an Early Adjuvant Treatment**

KBCSG 002

Objectives

Primary end point

To compare the overall QoL (Quality of Life) using Trial outcome index (TOI) of FACT-B questionnaire for 3 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.

KBCSG 002

Evaluation Schedule

Visit Number	1	2	3	4	5	6	7	8
Time of visit	1day	3M	6M	12M	18M	24M	30M	36M
Inclusion / Exclusion criteria	●							
Demographics/ Relevant medical history	●							
Dispense study medication	●	●	●	●	●	●	●	●
Adverse event record		●	●	●	●	●	●	●
QOL Survey (Fact-B etc)	●	●	●	●	●	●	●	●
Laboratory assessment (Including total Cholesterol)	●			●		●		●
BMD	●			●		●		●

한국유방암학회
KOREAN BREAST CANCER SOCIETY

Korean Hereditary Breast Cancer Study (KOHBRA, KBCSG 003)

- **Purpose**
  1. **To evaluate the prevalence of BRCA1/2 mutation of breast cancer patients with family history of breast/ovarian cancer.**
  2. **To evaluate the prevalence of BRCA1/2 mutation of breast cancer patients without family history, but high risk of hereditary cancer.**
  3. **To evaluate the prevalence of BRCA1/2 mutation of family member of BRCA1/2 mutation.**
  4. **To evaluate the prevalence of ovarian cancer of population of above 3 groups.**

- **Condition Breast Cancer, Ovarian Cancer**

- **Study Type: Observational Study**
- **Design:Cohort, Prospective**
- **Official Title: Korean Hereditary Breast Cancer Study**

KBCSG 003

Korean Hereditary Breast Cancer Study

1st subject

The prevalence of BRCA1/2 mutation of breast cancer patients with family history of breast/ovarian cancer

2nd Subject

The prevalence of BRCA1/2 mutation of breast cancer patients without family history, but high risk of hereditary cancer

3rd Subject

The prevalence of BRCA1/2 mutation of family member of BRCA1/2 mutation

4th Subject

The prevalence of ovarian cancer of population of above 3 groups

Prevalence of BRCA mutation

BRCA mutation carriers identified: 185

- **116 probands**
- **69 family members**

	1st subject	2nd subject	3rd subject	Total
Total	324	321	113	758
Mutation	83*	33*	69	185
Prevalence	25.6%	10.3%	61.1%	24.4%

A Clinical Trial of Paclitaxel Loaded Polymeric Micelle in Patients With Taxane-Pretreated Recurrent Breast Cancer (KBCSG 004)

- **Purpose**

  The purpose of this study is to evaluate the response rate in patients with taxane-pretreated recurrent breast cancer receiving paclitaxel loaded polymeric micelle (Genexol-PM).

- **Condition; Recurrent Breast Cancer**
- **Intervention; Drug: Paclitaxel loaded Polymeric micelle**
- **Phase; Phase IV**

- **Study Type: Interventional**
- **Study Design: Treatment, Open Label, Single Group Assignment, Safety/Efficacy StudyOfficial**
- **Title: A Clinical Trial of Paclitaxel Loaded Polymeric Micelle (Genexol-PM®) in Patients With Taxane-Pretreated Recurrent Breast Cancer**

Title & Objectives

Title

A Clinical Trial of Paclitaxel Loaded Polymeric Micelle (Genexol-PM®) in Patients With Taxane-Pretreated Recurrent Breast Cancer

Objectives

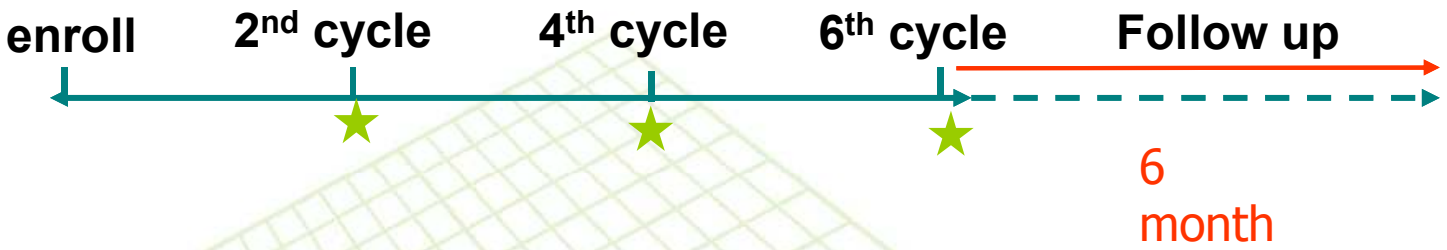
1ry Objective : Response Rate

2ndry Objectives : Progress Free Survival

Toxicity

Design

- Open, Prospective, multicenter trial
- 6 cycles(18 weeks) treatment



- Repeat cycle every 3 weeks
- Delay cycle for maximum 2 weeks if patient does not recover from the toxicity
- Evaluation: every 2 cycles(2, 4, 6 cycle)

Evaluating the Role of the Addition of Ovarian Function Suppression (OFS) to Tamoxifen in Young Women (ASTRRA, KBCSG 005)

- **Purpose**

  The purpose of this study is 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 after neo-/adjuvant cytotoxic chemotherapy and the hormone receptor positive breast cancer patients who were treated with Tamoxifen.

- **Condition; Breast Cancer**
- **Intervention**

  Drug: goserelin

  Drug: tamoxifen
- **Phase; Phase III**

- **Study Type:Interventional**
- **Study Design:Treatment, Randomized, Open Label, Factorial Assignment, Safety/Efficacy Study**
- **Official Title: A Randomised Phase III Study for Evaluating the Role of the Addition of Ovarian Function Suppression to Tamoxifen in Young Women With Hormone-Sensitive Breast Cancer Who Remain in Premenopause or Regain Menstruation After Chemotherapy**

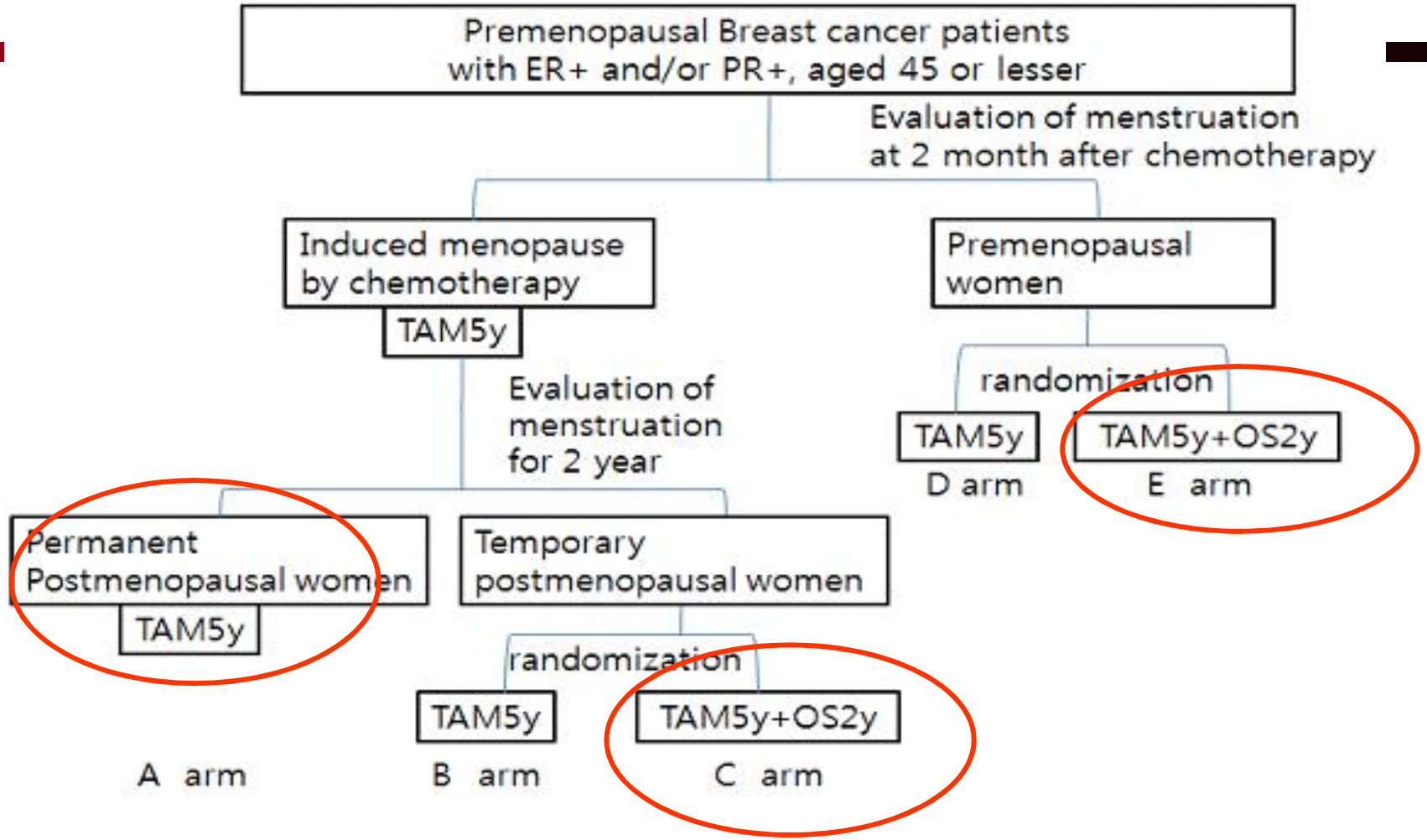
KBCSG 005

Key question still remains unanswered

- Does the addition of ovarian suppression provide extra benefit in those women who continue to menstruate or regain menstruation after chemotherapy?

KBCSG 005

Study design



Expected Results: A = C = E > B =D

CREATE-X(Capecitabine for REsidual cancer as Adjuvant ThErapy – X)

- **Purpose**

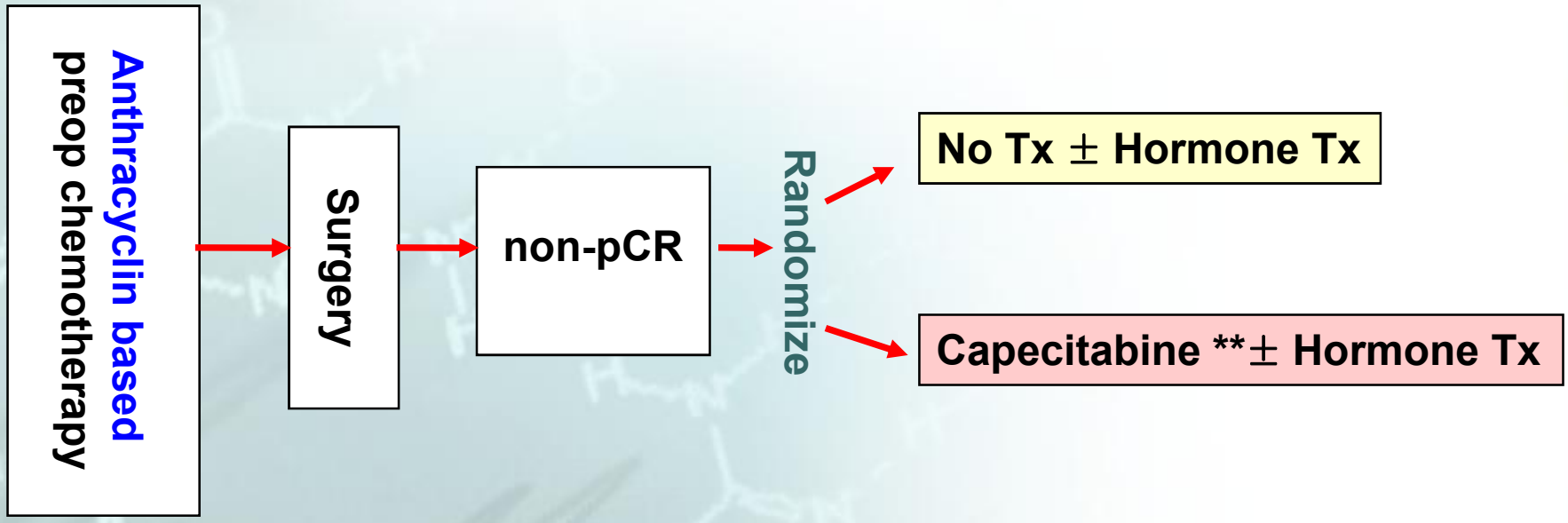
  This study is designed to investigate the efficacy and safety of capecitabine, as a postoperative adjuvant chemotherapy, for breast cancer patients who have pathologic residual cancer cells after the preoperative chemotherapy. In addition, the cost-effectiveness of capecitabine is to be investigated.

- **Condition; Breast Cancer**
- **Intervention; Drug: capecitabine**
- **Phase; Phase III**

- **Study Type:Interventional**
- **Study Design:Treatment, Randomized, Open Label, Factorial Assignment, Safety/Efficacy Study**
- **Official Title: A phase III randomized study of capecitabine as adjuvant chemotherapy versus observation in breast cancer with pathologic residual tumors after preoperative chemotherapy**

CREATE-X

Design



**Capecitabine 6 cycles every 3 weeks

Perspectives

- Tissue Bank
- Global networking – international cooperation with global trial group
- Develop international trials for Asian breast cancer patients