CIRG

Countries: Canada, France, USA

Group: Cancer International Research Group **(CIRG)**

Scientific Committee Chair:
D. Slamon
Division of Hematology/Oncology
David Geffen School of Medicine at UCLA
10945 Le Conte Avenue, Suite 3360
Los Angeles, CA 90095
USA
Tel: +1 310 825 5193
Fax: +1 310 267 2301
Email: dslamon@mednet.ucla.edu

CIRG Central Headquarters:
Edmonton Office:
Suite 1100
9925-109 St.
Edmonton, ALBERTA T5K 2J8
CANADA
Tel: +1 780 702 0200
Fax: +1 780 702 0190

CIRG Satellite Offices:
Paris Office:
13, rue Martin Bernard
PARIS 75013
FRANCE
Tel: +33 1 58 10 09 09
Fax: +33 1 58 10 08 77
Email: contact@cirg.org (for all general inquiries and information)

Medical Officer:
D. Slamon
Division of Hematology/Oncology
David Geffen School of Medicine at UCLA
10945 Le Conte Avenue, Suite 3360
Los Angeles, CA 90095
USA
Tel: +1 310 825 5193
Fax: +1 310 267 2301
Email: dslamon@mednet.ucla.edu

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Chief Operating Officer Executive: M.-A. Lindsay
Suite 1100
9925-109 St.
Edmonton, ALBERTA T5K 2J8
CANADA
Tel: +1 780 702 0223
Fax: +1 780 702 0190
Email: mary-ann.lindsay@cirg.org

Manager of Communications: E. Mékercke
Tel: +33 1 58 10 08 97
Fax: +33 1 58 10 09 12
Email: emmanuelle.mekercke@cirg.org

Website: www.cirg.org

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Title: A multicenter phase III randomized trial comparing docetaxel in combination with doxorubicin and cyclophosphamide (TAC) *versus* doxorubicin and cyclophosphamide followed by docetaxel (A → CT) as adjuvant treatment of operable breast cancer her2neu-negative patients with positive axillary lymph nodes.
CIRG 005

Coordinator(s): W. Eiermann
Red Cross Women Hospital
Fauenklinik vom Roten Kreuz, I Gyngebh. Abt./Taxisstr. 3
MUNCHEN 80637
GERMANY
Tel: +49 89 15 70 66 20
Fax: +49 89 15 70 66 23
Email: w.eiermann@gmx.net

J. Mackey
Northern Alberta Breast Cancer Program
Cross Cancer Institute
11560 University Avenue
Edmonton, ALBERTA T6G 1Z2
CANADA
Tel: +1 780 432 8792
Fax: +1 780 432 8526
Email: johnmack@cancerboard.ab.ca

J. Crown
St Vincent Consulting Private Clinic
Herbert Avenue, Marian Road
DUBLIN 4
IRELAND
Tel: +353 1 209 4895
Fax: +353 1 283 7719
Email: JOHN.CROWN@ICORG.IE

Summary:

- Start date: September 2000
- Enrollment completed: February 2003
- Final accrual: 3298 patients

Primary Objective:

- Disease-free survival.

Secondary Objective:

- Overall survival, toxicity and quality of life, pathologic and molecular markers, socioeconomics.

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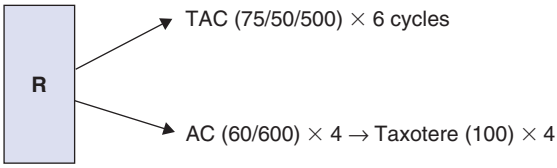
Scheme:

Patient Population:

Node-positive
Adjuvant breast cancer
her2neu negative (centrally confirmed by FISH)

Randomization:

Stratify
- Number of nodes (1−3, 4+)
- Center



Update:

- The results of the first interim analysis were presented at the San Antonio Breast Cancer Symposium on December 2005, by Dr Eiermann (Poster Session #1069). The safety results were presented and are available on the SABCS and CIRG websites. Additional follow-up is required by the IDMC to evaluate the relative efficacy of combination *versus* sequential docetaxel-containing chemotherapy in the adjuvant treatment of women with node-positive, her2 breast cancer. Efficacy results will be presented at the final analysis planned Q1, 2008.

Related Publications: None available

Topics:

- her2-negative patients
- Node-positive breast cancer
- Taxanes

Keywords: Adjuvant, node-positive, her2 negative, docetaxel, sequential, combination of taxanes and anthracyclines

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Title: Multicenter phase III randomized trial comparing doxorubicin and cyclophosphamide followed by docetaxel (AC → T) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (AC → TH) and with docetaxel, carboplatin and trastuzumab (TCH) in the adjuvant treatment of node-positive and high-risk node-negative patients with operable breast cancer containing the her2neu alteration.
BCIRG 006.

Coordinator(s): D. Slamon
Division of Hematology/Oncology
David Geffen School of Medicine at UCLA
10945 Le Conte Avenue, Suite 3360
Los Angeles, CA 90095
USA
Tel: +1 310 825 5193
Fax: +1 310 267 2301
Email: dslamon@mednet.ucla.edu

J. Crown
St Vincent Consulting Private Clinic
Herbert Avenue, Marian Road
DUBLIN 4
IRELAND
Tel: +353 1 209 4895
Fax: +353 1 283 7719
Email: john.crown@icorg.ie

Dr T. Pienkowski
Memorial Cancer Centre – Institute of Oncology
Breast Cancer Clinic
5 Roentgena St.
02-781 WARSAW
POLAND
Tel: +48 22 644 0024
Fax: +48 22 644 0024
Email: tpien@coi.waw.pl

Summary:

- Enrollment start date: April 2001
- Enrollment completed: March 2004
- Final accrual: 3222 patients
- Planned interim cardiac analyses after 300, 900 and 1500 patients have received chemotherapy treatment and 6 months follow-up.

Primary Objective:

- Disease-free survival.

Secondary Objective:

- Overall survival, toxicity and quality of life, pathologic and molecular markers, socioeconomics.

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Scheme:

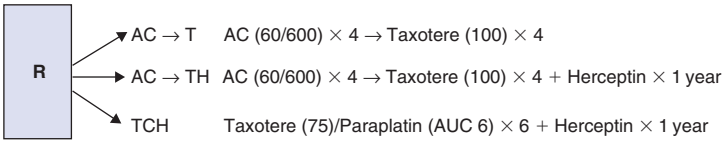
Patient Population:

- Node-positive
- Adjuvant breast
- High-risk node-negative
- Her2neu positive (centrally confirmed by FISH in BCIRG laboratories)

Randomization:

Stratify

- Number of nodes (0, 1–3, 4+)
- Center



Update:

- The results from the first interim efficacy (at 322 events) and updated safety analyses were presented at the San Antonio Breast Cancer Symposium on December 2005, by Dr D. Slamon (Abstract #1) and are available on the CIRG website. Result of this trial confirms the benefit of Herceptin (H) when combined with docetaxel (AC-TH) or with docetaxel and carboplatin (TCH) without an anthracycline. There are fewer severe cardiac adverse events when H is administered without prior A. Longer follow-up is needed in order to confirm whether non-A-based adjuvant H regimens will have efficacy comparable to A-based regimens. Second interim analysis will present efficacy and safety results.

Related Publications: None available

Topics:

- Axillary lymph node dissection
- Cardiac function
- her2-positive patients
- Node-negative breast cancer
- Node-positive breast cancer
- Sentinel node resection
- Tamoxifen
- Trastuzumab
- Taxanes

Keywords: Adjuvant, HER2, Herceptin

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Title: A multicenter phase III randomized trial comparing docetaxel (Taxotere) and trastuzumab (Herceptin) with docetaxel (Taxotere), platinum salt (cisplatin or carboplatin) and trastuzumab (Herceptin) as first line chemotherapy for patients with advanced breast cancer containing the her2neu alteration.
BCIRG 007

Coordinator(s): J. Crown
St Vincent Consulting Private Clinic
Herbert Avenue, Marian Road
DUBLIN 4
IRELAND
Tel: +353 1 209 4895
Fax: +353 1 283 7719
Email: john.crown@icorg.ie

V. Valero
University of Texas MD Anderson Cancer Ctr
1515 Holcombe Blvd Unit 424
Houston, TX 77030-0056
USA
Tel: +1 713 792 2817
Fax: +1 713 794 4385
Email: vvalero@mdanderson.org

D. Slamon
Division of Hematology/Oncology
David Geffen School of Medicine at UCLA
10945 Le Conte Avenue, Suite 3360
Los Angeles, CA 90095
USA
Tel: +1 310 825 5193
Fax: +1 310 267 2301
Email: dslamon@mednet.ucla.edu

Summary:

- Enrollment start date: December 2001
- Enrollment completed: March 2004
- Final accrual: 263 patients

Based on preclinical synergy seen between docetaxel (T), carboplatin (C) and trastuzumab (H), BCIRG conducted a randomized multicenter phase III trial in women with her2-positive MBC to evaluate the efficacy and safety of H regimens in combination with T or TC.

Primary Objective:

- Time to disease progression.

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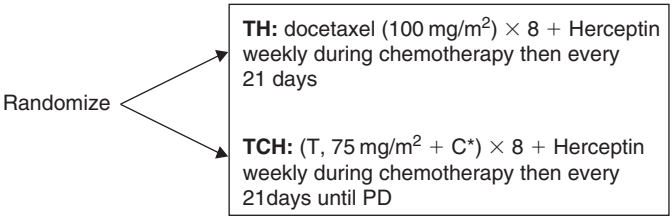
Secondary Objectives:

- To compare response rate, duration of response, overall survival.
- To evaluate and compare clinical benefit, defined as CR, PR or stable disease >24 weeks.
- To compare toxicity between the two arms.
- To evaluate pathologic and molecular markers for predicting efficacy.
- To compare peripheral levels of shed her2neu extracellular domain (ECD) with FISH determination in predicting outcome to treatment with Herceptin.

Scheme:



Update:

- CIRG randomized 263 patients with her2 FISH + MBC; 131 patients were treated in each arm. Dr Forbes (from the trial ANZ BCTG group) presented results of safety and the TTP analysis conducted after 204 events at ASCO 2006. Additional information presented at ESMO (148PD)

Related Publications: None available

Topics:

- Cardiac function
- her2-positive patients
- Metastatic breast cancer
- Taxanes
- Trastuzumab

Keywords: MBC, trastuzumab, docetaxel

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