https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press

Country: Japan

Group: Japan Breast Cancer Research Group **(JBCRG)**

Chair: M. Toi
Tokyo Metropolitan Cancer and Infectious Disease Center
Komagome Hospital
3-18-22, Honkomagome
Bunkyo-ku
TOKYO 113-8677
JAPAN
Tel: +81 3 3823 2101
Email: maktoi77@wa2.so-net.ne.jp

https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press

Title: Study of CEF-DOC as primary systemic chemotherapy for operable breast cancer.

Coordinator(s): M. Toi
Tokyo Medical Center for Cancer and Infectious Diseases
Komagome Hospital
3-18-22, Honkomagome, Bunkyo-ku
TOKYO 113-8677
JAPAN
Tel: +81 3 3823 2101
Fax: +81 3 3824 1552
Email: maktoi77@wa2.so-net.ne.jp

Summary:

- Opened in July 2002
- Target accrual: 200 patients

Primary Objective:

- Clinical response, pathological response.

Secondary Objective:

- Molecular changes in apoptosis-related molecules, drug-resistance related molecules.

Scheme: *Regimen:*

CEF (500 mg/m^2, 100 mg/m^2, 500 mg/m^2)
q 3 × 4 cycles → Docetaxel (75 mg/m^2) q 3 × 4 cycles

Update:

- Closed (reached) target accrual (202). This study forms the basis for other trials of JBCRG; JBCRG02, Phase II neoadjuvant trial looking at the efficacy of FEC followed by docetaxel100 for primary breast cancer patients; JBCRG03, Phase II neoadjuvant trial looking at the efficacy of docetaxel75 followed by FEC for primary breast cancer patients. These studies are registered at the UMIN Clinical Trial Registry (CTR), http://www.umin.ac.jp/english/

Related Publications:

Iwata H, Nakamura S, Toi M *et al.* Interim analysis of a phase II trial of cyclophosphamide, epirubicin and 5-fluorouraci (CEF) followed by docetaxel as preoperative chemotherapy for early stage breast carcinoma. *Breast Cancer* 2005; 12(2): 99–103.

Kuroi K, Toi M, Tsuda H *et al.* From the Japan Breast Cancer Research Group (JBCRG): How to define pCR: Our challenge. *BIG Newslett* 2005; 7(1): 17.

https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press

Kuroi K, Toi M, Tsuda H *et al.* Unargued issues on the pathological assessment of response in primary systemic chemotherapy. *Biomed Pharmacother* 2005; 59 (Suppl II) (1st OOTR mini-review).

Kuroi K, Toi M, Tsuda H *et al.* Issues in the assessment of the pathologic effect of primary systemic therapy for breast cancer. *Breast cancer* 2006; 13(1): 38–48.

Ohno S, Toi M, Kuroi K *et al.* Update results of FEC followed by docetaxel neoadjuvant trials for primary breast cancer. *Biomed Pharmacother* 2005; 59 (Suppl II): S323–S324 (1st OOTR).

Topics:

- Anthracyclines
- Perioperative chemotherapy

Keywords: Primary systemic chemotherapy, breast cancer

https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press

Title: Study of FEC-DOC100 as primary systemic chemotherapy for operable breast cancer.

Coordinator(s): S. Nakamura
Breast center
St Luke's International Hospital
9-1 Akashi, Tyuo-ku
TOKYO 104-8560
JAPAN
Tel: +81 3 3534 5151
Fax: +81 3 55507022
Email: seigonak@luke.or.jp

Summary:

- Opened in August 2004
- Target accrual: 30 patients

Primary Objective:

- Safety, clinical and pathological effect.

Secondary Objective:

- Breast-conserving rate, disease-free survival.

Scheme: *Regimen:*

FEC (500 mg/m^2, 100 mg/m^2)
q 3 × 4 cycles → Docetaxel (100 mg/m^2)
q 3 × 4 cycles

Update:

- Closed (reached) target accrual (31). This study is registered at the UMIN Clinical Trial Registry (CTR), http://www.umin.ac.jp/english/

Related Publications:

Iwata H, Nakamura S, Toi M *et al.* Interim analysis of a phase II trial of cyclophosphamide, epirubicin and 5-fluorouracil (CEF) followed by docetaxel as preoperative chemotherapy for early stage breast carcinoma. *Breast Cancer* 2005; 12(2): 99–103.

Kuroi K, Toi M, Tsuda H *et al.* From the Japan Breast Cancer Research Group (JBCRG): How to define pCR: Our challenge. *BIG Newslett* 2005; 7(1): 17.

Kuroi K, Toi M, Tsuda H *et al.* Unargued issues on the pathological assessment of response in primary systemic chemotherapy. *Biomed Pharmacother* 2005; 59 (Suppl II) (1st OOTR mini-review).

https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press

Kuroi K, Toi M, Tsuda H *et al.* Issues in the assessment of the pathologic effect of primary systemic therapy for breast cancer. *Breast Cancer* 2006; 13(1): 38–48.

Ohno S, Toi M, Kuroi K *et al.* Update results of FEC followed by docetaxel neoadjuvant trials for primary breast cancer. *Biomed Pharmacother* 2005; 59 (Suppl II): S323–S324 (1st OOTR).

Topics:

- Anthracyclines
- Perioperative chemotherapy

Keywords: Primary systemic chemotherapy, breast cancer, pCR

https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press

Title: DOC-FEC as primary systemic chemotherapy.

Coordinator(s): H. Iwata
Aichi Cancer Center Hospital
Department of Breast Oncology
1-1 Kanokoden, Chikusa-ku
NAGOYA 464-8681
JAPAN
Tel: +81 52 762 6111
Fax: +81 52 764 2963
Email: hiwata@aichi-cc.jp

Summary:

- Opened in October 2005
- Target accrual: 130 patients

Primary Objective:

- Pathological response, safety.

Secondary Objective:

- Clinical response, breast-conserving rate, overall survival, disease-free survival.

Scheme:

Regimen:

Docetaxel (75 mg/m^2)
q 3 × 4 cycles → FEC (500 mg/m^2, 100 mg/m^2) q 3 × 4 cycles

Update:

- Ongoing.
- This study is registered at UMIN Clinical Trial Registry (CTR), http://www.umin.ac.jp/english/

Related Publications:

Iwata H, Nakamura S, Toi M *et al.* Interim analysis of a phase II trial of cyclophosphamide, epirubicin and 5-fluorouraci (CEF) followed by docetaxel as preoperative chemotherapy for early stage breast carcinoma. *Breast Cancer* 2005; 12(2): 99–103.

Kuroi K, Toi M, Tsuda H *et al.* From the Japan Breast Cancer Research Group (JBCRG): How to define pCR: Our challenge. *BIG Newslett* 2005; 7(1): 17.

Kuroi K, Toi M, Tsuda H *et al.* Unargued issues on the pathological assessment of response in primary systemic chemotherapy. *Biomed Pharmacother* 2005; 59 (Suppl II) (1st OOTR mini-review).

Kuroi K, Toi M, Tsuda H *et al.* Issues in the assessment of the pathologic effect of primary systemic therapy for breast cancer. *Breast Cancer* 2006; 13(1): 38–48.

https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press

Ohno S, Toi M, Kuroi K *et al.* Update results of FEC followed by docetaxel neoadjuvant trials for primary breast cancer. *Biomed Pharmacother* 2005; 59 (Suppl II): S323–S324 (1st OOTR).

Topics:

- Anthracyclines
- Perioperative chemotherapy

Keywords: Primary systemic chemotherapy, breast cancer

https://doi.org/10.1017/S147090310600928X Published online by Cambridge University Press