SAKK

Country: Switzerland

Group: Swiss Group for Clinical Cancer Research **(SAKK)** – Breast Cancer Project Group

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https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Title: Randomized phase III trial of Herceptin followed by chemotherapy plus Herceptin *versus* the combination of Herceptin and chemotherapy as palliative treatment in patients with HER2-overexpressing advanced/metastatic breast cancer.
Protocol SAKK 22/99

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Summary: *Primary Objective:*

- To compare efficacy, toxicity and quality of life of the sequential administration of Her alone followed, at PD, by the combination with Chemotherapy (Arm A) *versus* the upfront combination of Herceptin and Chemotherapy (Arm B) in patients with advanced/metastatic breast cancer.

Secondary Objective:

- To investigate the predictive value of serum HER2/neu ECD levels on clinical outcome, the effects of Her on estrogen receptor, and the association of immunoprofiles of erbB-1, erbB-2, erbB-3 and erbB-4 with clinical outcome.

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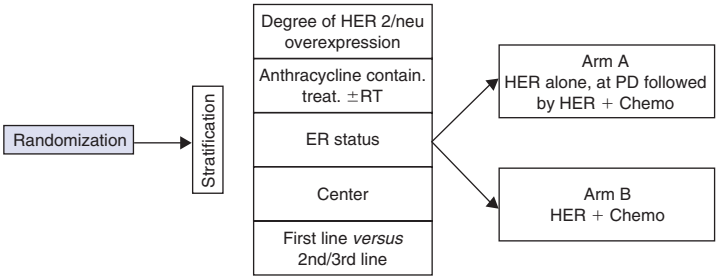
Scheme:



Update:

- Activation date: 30 August 1999.
- Accrual at the end of September 2006: 100 patients.

Related Publications: None available

Topics:

- HER2 positive patients
- Innovative schedules
- Metastatic breast cancer
- Predictive markers
- Taxanes
- Trastuzumab
- Vinorelbine
- Capecitabine

Keywords: Metastatic breast cancer, chemotherapy, targeted therapy, trastuzumab

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Title: Trastuzumab monotherapy followed by the combination of trastuzumab and letrozole in post-menopausal women with ER-positive, HER-2 positive advanced breast cancer resistant to a nonsteroidal aromatase inhibitor.
A multicenter two-step phase II trial
Protocol SAKK 23/03

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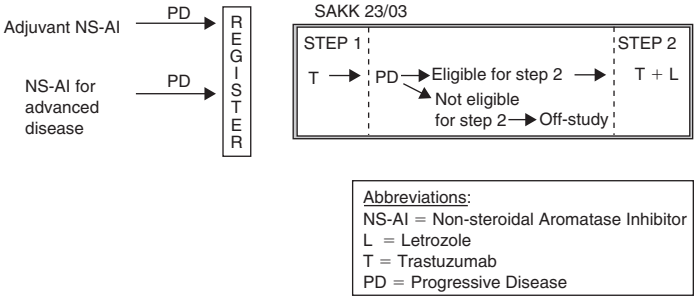
Summary: *Objectives:*

- *The primary objective* is to determine the efficacy of combined letrozole (L) and trastuzumab (T) in postmenopausal women with ER-positive, HER-2 positive advanced breast cancer resistant to sequential monotherapy of a nonsteroidal aromatase inhibitor followed by trastuzumab.
- *The secondary objectives* are to evaluate the safety profile of this combination by recording the adverse drug reactions and abnormal laboratory values during treatment and to investigate predictive markers for response to treatment with letrozole and trastuzumab in HER-2 positive, ER-positive positive tumors.

Scheme:



Update:

- Activation date: 12 May 2005.
- Accrual at the end of September 2006: 4 patients.

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Related Publications: None available

Topics:

- HER2 positive patients
- Hormonal therapy
- Hormone receptor positive breast cancer
- Innovative schedules
- Metastatic breast cancer
- Postmenopausal patients
- Predictive markers
- Trastuzumab
- Aromatase inhibitors

Keywords: Metastatic breast cancer, targeted therapy, trastuzumab, aromatase inhibitors, postmenopausal patients

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Title: Phase I–II trial of capecitabine and vinorelbine in elderly patients (>65 years) with metastatic breast cancer with and without bone involvement. **Protocol SAKK 25/99**

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Summary:

- In order to evaluate the influence on hematologic and mucosal toxicity, the protocol was divided into two trials, one including patients with bone involvement and one without.

Phase I:

- Identification of the maximum tolerated dose (MTD) of capecitabine and vinorelbine in elderly patients (>65 years) with metastatic breast cancer.

Phase II:

- Evaluation of the efficacy and tolerability of capecitabine and vinorelbine in elderly patients (>65 years) with metastatic breast cancer.
- As a secondary objective, to assess the time to treatment failure (TTF) of capecitabine and vinorelbine as a first line chemotherapy. Ultimately the goal of this trial was to assess the efficacy and toxicity of the tested dose levels and schedule in this elderly population as a "pilot" for a later adjuvant trial in high-risk elderly patients after surgical treatment.

Phase II End Points:

- Response rate, toxicity and time to treatment failure, quality of life.

Scheme:

- Capecitabine po d 1–14
- Vinorelbine iv d 1 and d 8
- Cycles to be repeated every 21 days for a maximum of 6 cycles

Update:

- Activation date: 10 March 1999.
- Accrual of patients with bone involvement closed on 8 December 2004: total accrual 46 patients.
- Accrual of patients without bone involvement closed on 7 September 2005: total accrual 24 patients.

Related Publications: Capecitabine and vinorelbine in elderly patients (⩾65 years) with metastatic breast cancer: a phase I trial (SAKK 25/99).

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Hess D, Thurlimann B, Pagani O *et al. Ann Oncol* 2004; 15: 1760–1765. Capecitabine and vinorelbine in elderly patients (> or = 65 years) with metastatic breast cancer: a phase I trial (SAKK 25/99)

Topics:

- Elderly patients
- Metastatic breast cancer
- Treatment tailoring
- Vinorelbine
- Capecitabine

Keywords: Metastatic breast cancer, elderly patients, chemotherapy, dose finding

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Title: Open multicenter phase II trial evaluating the antitumour efficacy of Faslodex (Fulvestrant) in postmenopausal women with advanced breast cancer failing non-steroidal or steroidal aromatase inhibitors.
Protocol SAKK 21/00

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Summary:

Primary Objective:

- Objective response rate (=CR + PR) of Faslodex treatment.

Secondary Objectives:

- Duration of clinical benefit (=CR + PR + SD ⩾ 24 weeks), time to progression, duration of response, time to treatment failure and safety and tolerability of Faslodex treatment.
- Objective response rate according to Her-2/*neu* status.

The trial involved *three levels of stratification*:

Stratum A:
Anastrozole or letrozole or aminoglutethimide responsive patients defined as patients who progressed while on anastrozole or letrozole or aminoglutethimide treatment given for advanced disease after initial objective response or disease stabilisation of at least 24 weeks.

Stratum B:
Anastrozole or letrozole or aminoglutethimide resistant patients defined as patients who did not respond to anastrozole or letrozole or aminoglutethimide given for advanced disease or showed disease stabilisation lasting less than 24 weeks.

Stratum C:
Eligible patients for whom strata A and B are not applicable, that is received anastrozole or letrozole or aminoglutethimide as adjuvant therapy.

Scheme: Faslodex (Fulvestrant) 250 mg intramuscular every month

Update:

- Activation date: 13 March 2000.
- Accrual closed on 23 June 2005: a total of 90 patients have been entered (25 in Switzerland).

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Related Publications: Perey L, Paridaens R, Hawle H *et al*. Clinical benefit of fulvestrant in postmenopausal women with advanced breast cancer and primary or acquired resistance to aromatase inhibitors: final results of phase II Swiss Group for Clinical Cancer Research Trial (SAKK 21/00). Annals of Oncology 2006; doi: 10.1093/annonc/mdl341

Topics:

- Hormone receptor positive breast cancer
- Metastatic breast cancer
- Postmenopausal patients
- Hormonal therapy

Keywords: Metastatic breast cancer, postmenopausal patients, endocrine treatment

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press

Title: Phase I/II trial of capecitabine with weekly paclitaxel for advanced breast cancer
Protocol SAKK 26/00

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Summary: *Objectives:*

- To identify the maximum tolerated dose (MTD) of capecitabine in combination with paclitaxel in patients with metastatic breast cancer.
  – *Phase I*: dose finding.
  – *Phase II*: evaluation of efficacy and toxicity.
- To test the dose just below the MTD identified in the phase I study for clinical efficacy and toxicity in the same population. The final goal is to find a well-tolerated drug combination for patients with metastatic breast cancer.

Scheme:

- Capecitabine po d 1–14
- Paclitaxel iv d 1, 8 and 15
- Cycles to be repeated every 21 days for a maximum of 6 cycles

Update:

- Activation date: 22 May 2000.
- Accrual closed on 21 September 2004: a total of 35 patients were enrolled.

Related Publications: None available

Topics:

- Metastatic breast cancer
- Treatment tailoring
- Capecitabine
- Taxanes

Keywords: Metastatic breast cancer, chemotherapy, dose finding

https://doi.org/10.1017/S1470903106009333 Published online by Cambridge University Press