

Study Design BR-01-2004

"Detection of circulating tumour cells in breast cancer: Performance evaluation study of the CE-marked in vitro diagnostic medical device AdnaTest BreastCancer"

Aims

- Early detection of metastases and recurrence and the advantage of the AdnaTest over standard methods in clinical routine laboratory
- Evaluation of the efficacy of neoadjuvant therapy by analyzing breast cancer patients prior and after therapy administration
- Prognostic and predictive value of the AdnaTest

Design

	Pre Neo	Neo +03	Pre OP	Post OP	03	06	09	12	15	18	21	24	27	30	33	36
group I	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
group II								x	x	x	x	x	x	x	x	x



- First blood withdrawal before surgery or radiotherapy with or without neoadjuvant chemotherapy (group I) or first blood withdrawal 12 to 24 month after breast cancer surgery (group II).
- Study duration: 3 years, .

Inclusion criteria

- Female, 18 to 60 years old, with breast cancer
- T1, T2, N+ or T3, T4

Cooperating centers

Dr. E. Solomayer, Dr. T. Fehm University of Tübingen, Gynaecological hospital;
Head: Prof. Dr. Wallwiener

PD Dr. S. Kaul University of Heidelberg, Onkological laboratory
Gynaecological hospital; Head: Prof. Dr. Sohn