# Synopsis

## Faslodex Observations during Regular Use for metastased Mammacarcinoma

FORUM
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BS081144

**Primary objective:**.
To test for clinically significant differences in Time to Treatment Failure (TTF) between patients with $ER^+PgR^+$ and patients with $ER^+PgR^-$ tumour status

**Secondary objectives:**
- To determine whether disease or tumour characteristics have an influence on the Time to Treatment Failure (TTF). This includes the following factors: treatment line, HER2/neu, WHO-status and Estrogen or progesterone receptor concentration in tumor-tissue.
- To test for interactions between any of those factors (if relevant).

**First Patient First Visit:**
25 July 2005.

**Last Patient Last Visit:**
10 October 2008.

**Number of patients:**
In total 87 patients were included in the study. Of these patients 83 were included in the efficacy analysis.

**Main criteria for inclusion:**
Postmenopausal women with locally advanced or metastatic hormone sensitive ($ER^+$ and/or $PgR^+$) breast cancer who according to their physician can start with 250 mg/5 ml Faslodex.

**Criteria for evaluation:**
Efficacy:
- Comparison of Time to Treatment Failure (TTF) between patients with $ER^+PgR^+$ and patients with $ER^+PgR^-$ tumor status.
- Influence of other baseline factors like treatment line, WHO-status, distant metastases, HER2/neu receptor status and receptor concentration on TTF.
- Patient evaluation of Faslodex treatment.

Safety:
- Treatment compliance and administration.
- All reported adverse events and serious adverse events.

**Results:**
The mean graphs and Kaplan-Meier curves indicate that the following factors might have a shortening effect on the TTF:
- administration as a $2^{nd}$ line of treatment
- WHO score 2 (compared to score 1 and 0)
- distant visceral metastases

In addition, the patients in the ER+PgR+ tumour group had a slightly longer mean TTF, a higher percentage of censored patients and a higher median TTF. This could indicate that those patients are more likely to have a response to Faslodex treatment.

Overall, two serious adverse events were reported in two patients. Both were reported to be related to the study drug.