

21-gene recurrence score® in patients with primary metastatic ER+ HER2- breast cancer

Barinoff J, Anastasiadou L, Brandi C, Junker-Stein A, Silbermann J, Langenfeld M, Fortmann C, Thill M Agaplesion Markus Krankenhaus, Frankfurt am Main/Germany; Klinikum Frankfurt Höchst, Frankfurt am Main/Germany; Genomic Health, Genève, Switzerland

Background and Purpose

Results from the 21-gene Recurrence Score (RS) are prognostic and predictive for recurrence in early breast cancer independent of clinical-pathological parameters. Prognostic information and distribution of RS in primary metastatic breast cancer (PMBC) was reported in a previous study by King et al but remains ultimately unclear in ER+ HER2- patients. We hypothesize that there is a prognostic correlation between RS and TTP/OS in PMBC independent of clinical-pathological parameters, and the objective of the study is to evaluate the test for that cohort.

Patients and Trial Design

Between 2004 and 2014, 150 patients with first diagnosis of ER+/HER2- PMBC were enrolled in a multicenter, prospectively collected database. Pretreatment breast tumor samples will be analyzed by using 21-gene RS. Minimum follow-up will be 24 months.

Methods and Statistical Analysis

Patient characteristics, time to first progression (TTP), overall survival (OS) and treatment modalities will be described. The association between RS risk groups and both TTP and OS will be assessed by Kaplan-Meier estimates and compared with the log-rank test. Multivariate Cox regression models will be utilized to adjust for covariates. Additionally, assessing correlation of RS results using RS cut offs of 18 and 30 and additionally of 11 and 25 as well as analysis of quantitative ER from Oncotype DX assay for patients treated first-line with endocrine therapy are planned.

First results are expected to be presented in 2017.

Contact information for people with a specific interest in the trial:

Dr. Jana Barinoff

barinoff.jana@googlemail.com.

Session: Ongoing Clinical Trials: Ongoing Trials -- Predictive & Prognostic Factors (5:00 PM-7:00 PM)

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