

Liquid biopsy based early breast cancer detection

SPAG6, NKX2-6, PER1 promoter methylation biomarker panel

Invention

Early breast cancer detection, most favorably in a pre-cancerous (*in situ*) state is critical for the course of the disease and its outcome. Currently, mammography screening is the standard method of medical prevention. However, the compliance among women

invited for mammography is low ranging from merely 20 to 89 percent depending on country and age group. Similar to colorectal cancer prevention by colonoscopy, a much easier and less stressful examination method might find stronger compliance.

Researchers of the University Medical Center of Aachen have identified biomarkers, which are suitable for detection of early breast cancer and its precancerous stages in blood, based on the measurement of both grade and intensity of CpG promoter methylation of i.e. the genes *SPAG6*, *NKX2-6* and *PER1*. A combination of two genes or the inclusion of other

genes (e.g. *DKK3* or *ITIH5*) may also apply. It is very likely that a blood-based test would increase compliance of women to medical prevention programs of breast cancer. In addition, this concept may allow to broaden prevention to elderly women (>70 years) who currently are not invited to mammography screening.

Commercial Opportunities

In April 2016, a blood-based early detection system for colon cancer has been approved by the FDA. The inventive biomarkers could be applied in an analogous way for breast cancer detection. Both tests have similar sensitivity and specificity, suggesting a good chance of the present test also to be approved in a similar setting. Notably, a key argument for the approval by the FDA has been the likelihood of increased acceptance by the relevant population thus reinforcing screening participation.

On behalf of the University of Aachen (RWTH Aachen), PROVendis offers a patent license as well as a research collaboration with licensing option.

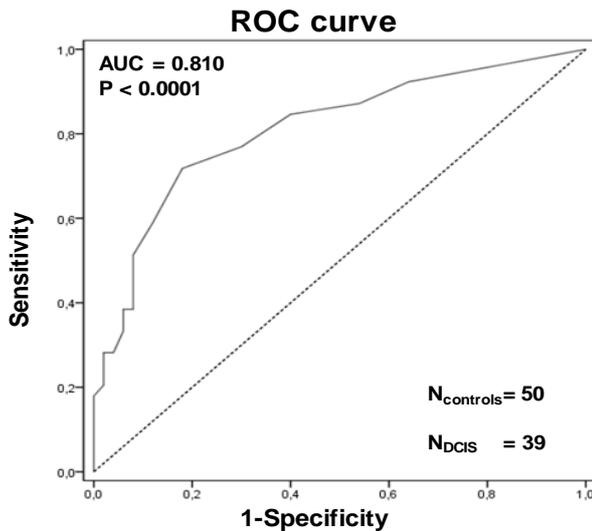
Current Status

The initial study included blood samples of 130 age-matched donors that comprised early breast cancer stages (T1N0M0), non-invasive DCIS (ductal carcinoma in situ) and healthy controls. The methylation intensity was measured by means of pyrosequencing. Currently, an additional 400 blood samples are being analyzed. In parallel, the inventors are establishing a NGS based protocol for methylation detection to improve the technical sensitivity. In case of interest we are pleased to inform you about the patent status.

An invention of the University Medical Center of Aachen (UKA).

Competitive Advantages

- Blood-based easy to perform pre-screen to current standard mammography
- Likelihood of much higher compliance of eligible women and consequently increasing screening participation



Analysis of 3-gene biomarker performance in patients (blood samples) with ductal carcinoma *in situ* (DCIS) as compared to normal donors (controls). Sensitivity reaches 70% at 80% specificity.

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