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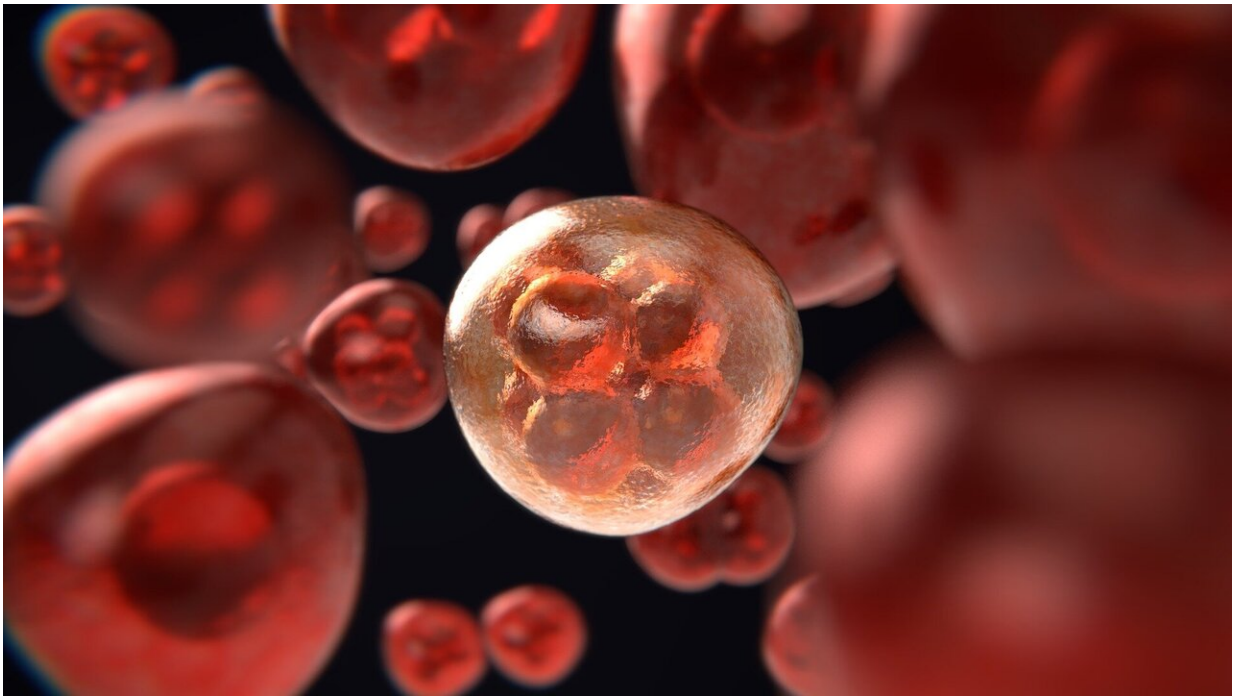
# Blood enzyme activity level may indicate which breast cancers are slow growing

September 14 2021



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Researchers with the SWOG Cancer Research Network have found that patients with metastatic hormone receptor-positive breast cancer who have low activity levels of the enzyme sTK1 in their blood serum at the start of anti-estrogen treatment live longer and go longer without their disease progressing than patients with high levels.

The results suggest that patients with low sTK1 activity levels have slow-growing disease that can be controlled initially with single-drug endocrine therapy for a prolonged period. It remains to be determined whether these patients gain further benefit from adding a CDK4/6 inhibitor to their endocrine therapy.

The findings come from an analysis of serum samples from 432 women with breast cancer who took part in the S0226 clinical trial, which was conducted by the SWOG Cancer Research Network, a cancer clinical trials group funded by the National Cancer Institute (NCI), part of the National Institutes of Health (NIH). Results are published today in *Clinical Cancer Research*, a journal of the American Association for Cancer Research.

"SWOG researchers have demonstrated that a blood serum test can identify which of these patients have slow-growing disease that might be controlled with a simple aromatase inhibitor pill alone," said Dr. Lajos Pusztai, MD, DPhil, professor of medicine (medical oncology) at Yale Cancer Center, who is a co-author on the paper.

Study S0226 found that most women with metastatic hormone receptor-positive breast cancer who have not had previous treatment for their metastatic breast cancer live longer when they get a combination of the endocrine therapy drugs anastrozole and fulvestrant than when they get just anastrozole.

However, not all patients see extra benefit from the combination; some do just as well on a single drug. Having a way to identify which patients would not derive added benefit from the combination could save these patients the additional side effects and extra costs associated with taking two drugs instead of one.

The work was led by Costanza Paoletti, MD, who was then with the

University of Michigan Rogel Cancer Center. She and her colleagues measured the level of serum thymidine kinase 1, or sTK1, considered a marker of cellular proliferation, in 1,726 samples taken from S0226 patients before the start of their treatment and at four time points during treatment. The samples were evaluated using a commercially available test known as the DiviTum assay, produced by Biovica International of Uppsala, Sweden, which measures levels of the enzymatic activity of sTK1. The researchers found what were considered high levels of the enzyme in samples from 171, or 40 percent, of the patients.

Patients with high sTK1 levels, either before treatment or at any time during treatment, tended to have a significantly shorter period of time before their disease advanced (progression-free survival time, or PFS). Those with high levels at the start of treatment, or baseline, had a median PFS of only 11.2 months compared to 17.3 months for patients with low levels at baseline. The high-sTK1 patients also died sooner, on average, than patients with low levels of the biomarker, with median overall survival times of just 30 months versus 58 months.

Importantly, patients with low sTK1 levels did just as well on the single drug anastrozole as on the combination. This means a measurement of pretreatment sTK1 level could potentially be used to determine whether a patient should start treatment with two-drug endocrine therapy (high sTK1) or a single-drug endocrine therapy (low sTK1).

The researchers also called for more investigation into whether low sTK1 levels could further indicate which patients could be spared having targeted therapy drugs added to their endocrine therapy.

Daniel Hayes, MD, also of the University of Michigan Rogel Cancer Center and a co-author on the paper, says, "These results should serve as the basis for future clinical studies to distinguish patients with estrogen receptor metastatic breast cancer who might be best treated with

endocrine therapy alone versus those who should receive endocrine therapy plus an ancillary treatment, such as CDK4/6, mTOR, or PIK3CA inhibitors. Each of these has been shown to complement endocrine therapy, but each is associated with additional side effects and costs."

**More information:** Costanza Paoletti et al, Evaluating Serum Thymidine Kinase 1 in Hormone Receptor Positive Metastatic Breast Cancer Patients Receiving First Line Endocrine Therapy in the SWOG S0226 Trial, *Clinical Cancer Research* (2021). DOI: 10.1158/1078-0432.CCR-21-1562

Provided by SWOG Cancer Research Network

Citation: Blood enzyme activity level may indicate which breast cancers are slow growing (2021, September 14) retrieved 6 May 2024 from https://medicalxpress.com/news/2021-09-blood-enzyme-breast-cancers.html

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