A new clinical trial is investigating a non-invasive, radiation-free imaging system that has the potential to help doctors more effectively determine which patients need biopsies.

How opto-acoustic imaging may improve breast cancer diagnosis.

Imagio uses a combination of traditional breast ultrasound with opto-acoustic imaging that provides physicians anatomical images of the breast and a “blood map” of a potentially suspicious mass.

Because cancerous tumors grow quickly, they require significant amounts of blood and oxygen, so a network of blood vessels will grow around the malignant lesion. Imagio images may identify vessel networks and the level of oxygen in the blood.

Radiologists believe that Imagio images depicting significant vessel structures and low oxygen levels are more likely to indicate cancer than images of masses without vessel networks and normal amounts of oxygen.

The potential improvement in the ability to rule out cancer would allow radiologists to more effectively differentiate between cancerous and benign masses, reducing the number of patients who are ultimately required to receive surgical or needle biopsies.

What is the PIONEER-01 study?

The PIONEER-01 Study (Pivotal Study of Imaging with Opto-acoustics to diagnose breast masses detected by mammography and/or clinical findings: a New Evaluation Tool for Radiologists – PIONEER-01) is a large study of opto-acoustic imaging that will include approximately 2,000 patients at 16 leading hospitals and breast imaging centers throughout the United States.

The study will be conducted over 16 months, 12 of which will be used for patient follow-up for non-biopsied patients.

Am I eligible to participate?

Participating centers are currently enrolling women 18 years and older who have suspicious breast masses. Patients are not eligible if they have had breast implants in the previous 12 months, are pregnant or have had a previous breast biopsy near the suspicious mass in the prior 18 months.

The PIONEER Study is sponsored by Seno Medical Instruments, Inc.

If I enroll in the study, what can I expect?

Women who enroll in the study will undergo a non-invasive, non-ionizing scan with Imagio following a traditional diagnostic breast ultrasound. The Imagio scan will only be used investigationally as a reference to compare the Imagio images to the biopsy results – or to the results of follow-up diagnostic imaging scans performed a year later if their lesion was not biopsied initially.

How can you or someone you love get involved?

If you or someone you know is interested in joining the study, please call: 866.573.5969

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