IMAging with opto-acoustics to downgradE BI-RADS claSsificaTion Relative tO other diagnostic methodologies (MAESTRO)

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This study is designed to determine whether the Imagio allows physicians to rapidly and effectively discern between benign and malignant masses with minimal potential side effects and therewith improve diagnostic efficiency. The study will evaluate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON41890

Source
ToetsingOnline

Brief title
MAESTRO-01

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
breast cancer, suspicious mass

Research involving
Human

Sponsors and support

Primary sponsor: Seno Medical Instruments, Inc.

Source(s) of monetary or material Support: Seno Medical Instruments Inc

Intervention

Keyword: BI-RADS, Breast cancer, Diagnostics, Imaging

Outcome measures

Primary outcome

For benign masses, to evaluate if the Imagio OA technology downgrades BI-RADS 4a and 4b classification as indicated by (Conventional Diagnostic Ultrasound) CDU to 3 or 2, for a potentially suspicious breast lesion after a diagnostic or screening evaluation.

For malignant masses, to evaluate that the Imagio OA technology does not lower the BI-RADS classification from 4a or 4b as determined by CDU to 3 or 2.

Secondary outcome

• To estimate the impact of blinding independent readers relative to the un-blinded site investigator(s).

• To compare and estimate that Imagio OA meets other acceptance metrics.

• To compare histologic relationships with Imagio OA findings for malignant masses.

• To assess the sensitivity and specificity of CDU and Imagio.

Imagio based nomograms that have been generated in a previous study will be assessed for their abilities to distinguish benign vs malignant and for their abilities to predict POM.

Study description

Background summary

Breast cancer is the most common cause of cancer-related death for women. Unfortunately, breast cancer remains difficult to definitively diagnose without performing a biopsy, despite the existence of multiple screening and diagnostic imaging methodologies: mammographic sensitivity declines with increasing breast density, conventional diagnostic ultrasound often results in false positives and biopsy of benign masses, color and power Doppler have a limited spatial resolution and are very user dependent.

The breast imaging challenge is to concurrently maximize the sensitivity and specificity in order to increase detection of breast cancer while decreasing the number of negative biopsies. This can lead to lower overall costs of imaging studies and biopsy procedures and less discomfort for the patient.
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The Imagio addresses this challenge by combining and co-registering opto-acoustics (OA) and conventional diagnostic ultrasound (CDU). The OA technology provides functional information with a high contrast and the CDU imaging provides anatomical information with a high spatial resolution. By combining both techniques in real time, more detailed information about the suspicious lesion can be obtained than by performing both techniques subsequently. Unlike other fused functional imaging modalities, Imagio does not require any injected contrast agent or radionuclide.

The OA technology provides information on the vascularization of the suspicious breast lesion and the oxidation of the blood. Malign and highly vascularized tissue deposits more light than benign and low vascularized tissue. Furthermore, red light (757nm) is absorbed predominantly by hypoxic (de-oxigenated) blood - typical for malign tissue, while near-infrared light (1064nm) is absorbed predominantly by normally oxygenated blood. By sending two pulses to the breast tissue, the change in the acoustic wave can be detected, and an indication can be made concerning the vascularization and oxidation. CDU can be used to form images of the internal soft tissue and architecture and density of the suspicious tissue can be revealed.

Several studies have previously been conducted. A proof of concept study provided information on the employed wavelengths in the OA technology. Furthermore, it was demonstrated that OA imaging is capable of not only visualizing shape and dimensions of blood vessels, but also differentiating deoxygenated blood from oxygenated blood. A total of 55 subjects were enrolled in an exploration study and the obtained data was used to refine the electro-mechanical design (including software and user interface) and to design a consistent algorithm. A feasibility study was conducted using a total of 155

subjects to evaluate whether the Imagio can be used to detect malign and benign features of lesions. Both internal and external features representing tumor morphology have been demonstrated. A subsequent system verification study was performed, enrolling a total of 42 subjects, to optimize image quality.
Currently, the expanded clinical study, PIONEER, is being conducted at 16 sites within the USA. The PIONEER has recently completed active enrollment of 2097 subjects.

Study objective

This study is designed to determine whether the Imagio allows physicians to rapidly and effectively discern between benign and malignant masses with minimal potential side effects and therewith improve diagnostic efficiency. The study will evaluate the ability to downgrade BI-RADS 4a or 4b masses to BI-RADS 3 or 2, classified by CDU, therefore potentially avoiding negative biopsies and short interval follow-up imaging studies.

Study design

This is a post-market, prospective, controlled, multi-center, and observational study in women with one or more tumors in the breast. Researchers will use the results of the conventional diagnostic ultrasound (CDU) for diagnosis and decision to start biopsy/excision. Results obtained with the Imagio will not be used as the reason to perform or to defer a biopsy or excision.

Subjects scheduled to undergo a biopsy following CDU will be prospectively evaluated with Imagio OA. The study will be explained to the subject after the biopsy decision has been made. Up to three suspicious masses for which the decision has been made to biopsy using CDU, from either breast, are acceptable candidate lesions for Imagio OA evaluation. All selected subjects will undergo an Imagio evaluation following consent and before any biopsy. The Imagio evaluation can be performed on the same day as the CDU, up to maximum 10 days after. Since all masses evaluated with Imagio OA will undergo biopsy, from which a definitive diagnosis will be obtained, no Imagio OA imaging follow up is required.
A total of approximately 200 subjects with masses classified as BI-RADS 4a or 4b by CDU will be prospectively enrolled (signed inform consent). The final number of subjects will be determined by an interim analysis after the first 75 subjects have been evaluated. The final sample size will require at least 140 benign and 70 malign masses.

The Principal Investigators (PI) and Sub-Investigators from each site will evaluate all cases in an un-blinded manner with access to patient clinical records, while three independent readers will evaluate all cases without access to patient clinical information. Each reader will estimate the probability of malignancy (POM) for each case, based on the CDU and Imagio imaging.

Additionally, an independent histopathologist will assess histologic features on the masses.

The impact of blinding the independent readers will also be assessed relative to the un-blinded site investigators.

Additionally, nomograms that have been generated in a previous study will be assessed for their abilities to distinguish benign from malignant and for their abilities to predict the POM.

Study burden and risks

In this study, the results of the Imagio scans do not determine whether or not biopsies need to be taken. The study participants will therefore not experience direct benefit. We hope that this study will contribute in the future to an accurate and early detection of breast cancer. If valuable, the Imagio may contribute to a reduction in the number of biopsy procedures to be performed. Consequently, less patients will suffer from physical and emotional stress around the biopsy procedure and waiting period to get the result from the pathologist.

List of potential risks and discomforts:
• Tingling or warmth of the skin during the Imagio scan (0.4% or a 1 in 269 chance) that resolve at completion of the scan
• Exposure to the laser of the Imagio* (to both skin and eyes)
• Exposure to the acoustic output
• Contamination due to insufficient cleaning materials
• Photoxicity when applying fragrance or lotion to the skin prior to scanning

The laser energy will be set to a level that is known as being below known harmful levels which is unlikely to harm the breast or give any discomfort. Also, everyone in the examination room will be wearing protective eyewear in order to minimize risk of damage by laser light to the eyes.

Seno Medical Instruments, Inc. believes that any potential risk presented by this investigation has been minimized and that adequate testing, safeguards, and safety monitoring have been incorporated into the investigation to further minimize and mitigate the risks.

Seno Medical Instruments, Inc. believes that the value of the knowledge to be gained by conducting this clinical investigation to demonstrate the clinical value of the Imagio* Breast Imaging System outweighs the potential risks posed to participating subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects must meet all of the following criteria to be included in the study:
1. Have been informed of the nature of the study and provided written informed consent, prior to initiation of any study activities;
2. Have an undiagnosed suspicious finding which may include more than one solid or complex cystic suspicious mass, classified by CDU as BI-RADS 4a or 4b within 3 weeks of their baseline Imagio Scan;
3. Are females 18 years of age or older at the time of consent;
4. Are willing and able to complete all procedures and assessments in accordance with the clinical protocol; and,
5. Have received recommendation for and are scheduled for an image-guided CNB, DVAB, or excisional biopsy of at least one mass.
6. Are willing to have an image-guided CNB, DVAB, or excisional biopsy within 30 days

following Imagio evaluation of the breast mass.

Exclusion criteria

Subjects who meet any of the following criteria will be excluded from the study:
1. Are males;
2. Are prisoners;
3. Have a condition or impediment that could interfere with the intended field of view (within one probe length or 4 cm of the mass), (i.e., breast implants within the previous 12 months, or tattoos);
4. Have or have had previously treated (i.e., lumpectomy, partial mastectomy, radiation therapy) cancer in the ipsilateral breast within the same quadrant(s) as the mass(es) to be biopsied;
5. Have had prior benign excisional breast biopsy within the immediate vicinity (within one probe length or 4 cm of the mass) of the currently evaluated suspicious mass within the past 18 months.
6. Have greater than 3 masses recommended for biopsy at baseline;
7. Patient had a previous diagnostic ultrasound of the suspicious mass greater than 3 wekks from the patient*s baseline Imagio scan;
8. Have no mass(es) characterized as BI-RADS 4a or 4b as determined by CDU;
9. Mass to be biopsied is greater than 3.0 cm in maximum diameter;
10. Patient currently has mastitis;
11. Patient has focal pain without thickening or mass within one probe length or 4 cm of the mass;
12. Is pregnant or lactating or planning to become pregnant during study participation;
13. Have open sores including insect bites, rash, poison ivy, and chafing on the skin of the ipsilateral breast within one probe length or 4 cm of the mass;
14. Have an acute or a chronic hematoma and/or acute ecchymosis of the ipsilateral breast;
15. Is experiencing photo-toxicity or photo-sensitivity or is undergoing treatment for a photo-sensitive condition such as porphyria or lupus erythematosus;
16. Patient has received chemotherapy for any type of cancer within 90 days from date of screening CDU;
17. Have had previous image guided CNB, image guided DVAB, or surgical biopsy of the target mass of interest;
18. Have nipple rings that cannot be removed or are not able to be removed during Imagio OA evaluation or infection or inflammation of the nipple ring area;
19. Patient has participated in a clinical study of an investigational drug or device within 3 months prior to screening CDU that may have an impact on clinical outcomes; and,
20. Patient has previously participated in this study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-05-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	22-12-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL51491.091.14