A Multi-Center InternatiONal Registry to Evaluate the Efficacy oF Imaging with Opto-acoustics to Diagnose BrEast CaNCEr

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The objective of this post market surveillance registry is to assess whether the Imagio OA/US technology for the indication of breast mass/focal finding diagnosis provides performance characteristics that could be used for worldwide clinical...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON46537

Source
ToetsingOnline

Brief title
CONFIDENCE-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: Breastmass diagnosis, Imagio OA/US technology imaging, postmarket

Outcome measures

Primary outcome

The primary endpoint of this post market surveillance registry is to provide the real world evidence on the specificity (SP) and negative likelihood ratio (NLR) and the sensitivity (SN) and positive likelihood ratio (PLR) of the Imagio OA/US technology for the indication of breast mass diagnosis as opposed to conventional diagnostic ultrasound (CDU) alone.

Secondary outcome

1. To assess the Imagio ultrasound (IUS) ± OA/US vs CDU (if available) for breast imaging findings classified as Breast Imaging-Reporting and Data System (BI-RADS 1) and 2 through a descriptive summary of test operating characteristics with the subpopulations of subjects presenting with breast imaging findings classified as BI-RADS 1 and 2 based on screening or diagnostic mammography,

2. To assess a sample of BI-RADS 0 screening breast imaging findings (mammogram or automated screening ultrasound) with IUS and/or OA through descriptive summary of test operating characteristics with the subpopulations of subjects presenting with BI-RADS 0,

3. To assess Imagio OA/US*s ability to impact the decision to biopsy vs ultrasound (both IUS and CDU). Specifically, to assess Imagio OA/US*s ability to downgrade the BI-RADS 3, 4a and 4b masses to 3 or lower and to assess Imagio

OA/US*s ability to upgrade the BI-RADS category, assessed by mammography and IUS as BI-RADS 3 for malignancy or benign, to 4a or higher. The primary comparison will be between OA/US to IUS alone,

4. To assess subject quality of life using the Testing Morbidities Index (TMI) following biopsy or Imagio but prior to biopsy results, to determine the potential improvement when using OA/US to diagnose a mass vs biopsy. The distributions of TMI psychometric scores will be compared among groups defined by their final BI-RADS designation,

5. To assess the Senogram*s abilities to distinguish benign vs malignant and to predict Probability of Malignancy (POM), utilizing multiple logistic regression and related methodologies. OA and IUS feature scoring variables (Senogram*) are designed to distinguish benign vs. malignant.

1. To assess the Imagio ultrasound (IUS) ± OA/US vs CDU (if available) for imaging findings classified as BI-RADS 1 and 2 through a descriptive summary of test operating characteristics with the subpopulation of subjects presenting with breast imaging findings classified as BI-RADS 1 and 2 based on screening or diagnostic mammography and/or CDU if done,

2. To assess a sample of BI-RADS 0 screening breast imaging findings (mammogram or automated screening ultrasound) with IUS and/or OA/US through descriptive summary of test operating characteristics with the subpopulations of subjects presenting with BI-RADS 0,

3. To assess Imagio OA/US*s ability to impact the decision to biopsy vs

ultrasound (both IUS and CDU). Specifically, to assess Imagio OA/US*s ability to downgrade the BI-RADS 3, 4a and 4b benign masses to 3 or lower and to upgrade the BI-RADS category, of malignant masses assessed by mammography and IUS as BI-RADS 3 for malignancy or benign, to 4a or higher. The primary comparison will be between OA/US to IUS alone,

4. To assess subject quality of life using the Testing Morbidities Index (TMI) following biopsy or Imagio but prior to biopsy results, to determine the potential improvement when using OA/US to diagnose a mass vs biopsy. The distributions of TMI psychometric scores will be compared among groups defined by their final BI-RADS designation,

5. To assess the SenoGram*s abilities to predict Probability of Malignancy (POM This includes analysis of IUS and OA/US feature scoring variables The SenoGram is designed to distinguish between a benign vs. malignant diagnosis.

6. To assess the Imagio OA/US*s ability in comparison to all other imaging modalities to generate an improvement in sensitivity, specificity, upgrades, downgrades, PPV, NPV, NLR, and PLR.

7. To assess the Imagio OA/US*s ability, in patients who undergo regional lymph node (axillary, intramammary, internal mammary, internal jugular, supraclavicular) examination as an extension of the breast imaging examination, to better determine the decision to biopsy, improve sensitivity and specificity, upgrading and downgrading POM, and improve PPV, NPV, NLR, and PLR.

8. In malignant masses, correlation of IUS and OA/US feature scoring with histologic grade, hormone receptors Ki-67, HER2 IHC, and HER2 FISH receptors as well as with molecular subtypes of breast cancer using various classification

systems will also be assessed.

Study description

Background summary

Breast cancer is the most common cause of cancer-related death for women. According to the World Health Organization, the highest rate of breast cancer cases was observed in Europe in 2012. Unfortunately, breast cancer remains difficult to definitively diagnose without performing a biopsy, despite the existence of multiple screening and diagnostic imaging methodologies.

Imagio is a real*time fusion imaging system combining opto-acoustics and B-mode ultrasound. It is indicated for use by a qualified and trained healthcare provider for opto-acoustic (OA) evaluation; or conventional B-mode ultrasound, Pulsed-Wave Doppler, Color/Power Doppler, or combined mode evaluation of breasts in women who are referred for a diagnostic breast ultrasound work-up due to a suspicious mass (including both palpable and non-palpable) or an imaging finding (such as architectural distortion, asymmetry, or suspicious calcifications).

This device is not intended to be used as a replacement for mammographic screening or for definitive pathologic diagnosis. The Imagio is intended to support qualified healthcare professionals in the differentiation of benign from malignant breast lesions and to support them in their decisions.

Study objective

The objective of this post market surveillance registry is to assess whether the Imagio OA/US technology for the indication of breast mass/focal finding diagnosis provides performance characteristics that could be used for worldwide clinical adoption and economic coverage of the procedure.

Study design

This is a prospective, controlled, multi center observational international registry designed to evaluate if Imagio can be used to downgrade and upgrade BI-RADS classification using either biopsy histology results or the decision to monitor subjects via follow up as applicable, as measure of truth. Investigators will perform Imagio ultrasound and/or OA/US imaging and any additional imaging and a biopsy (as applicable) at follow-up to reach a final diagnosis.

Subjects will be prospectively evaluated with Imagio IUS and/or OA/US. The

registry will be explained to the subject after the decision to use Imagio has been made, but before Imagio is performed. Subjects for whom the decision has been made to use the Imagio and have acceptable candidate masses for Imagio evaluation, will be included. All selected registry subjects will undergo an Imagio evaluation after signing the informed consent form (ICF). Imagio imaging follow-up will be required at 12 and 24 months as applicable per BI-RADS classification and standard of care.

Study burden and risks

Subjects enrolled in this study will not receive any care different than the standard of care with the exception of sites that do a breast cytological biopsy as standard of care, patients who have to undergo biopsy will undergo a histological biopsy in addition to or instead of a cytological biopsy depending on the sites practices. The histological biopsy results will be used for the study.

Contacts

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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Have been informed of the nature of the registry and provided written informed consent, prior to initiation of any registry activities,
2. Are males or females 18 years of age or older at the time of consent,
3. Either have a BI-RADS 1 mammogram (50 subjects) or have been referred for a breast ultrasound because of a breast mass/finding found (2100 subjects) on at least one of the following examinations:
a. Physical palpation or other signs symptoms (i.e. nipple discharge, skin changes, inflammation, etc.),
b. Screening or diagnostic mammography (including 2D mammography or tomosynthesis, CESM),
c. Supplemental screening ultrasound exam and/or CDU,
d. Screening or diagnostic breast MRI,
e. Screening or diagnostic molecular breast imaging (MBI technetium 99m sestamibi scans of the breast),
f. Screening or diagnostic PET/CT or PEM,
4. Be willing and able to complete all procedures and assessments in accordance with the clinical protocol,
5. Have up to 3 target mass(es) total per subject.

Exclusion criteria

1. Have a condition or impediment that could interfere with the intended field of view (within one probe length or 4 cm of the mass),
2. Mass(es) not visible under screening or diagnostic ultrasound (includes Imagio IUS)
3. Are pregnant,
4. 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 each mass to be included,
5. Are experiencing photo-toxicity or photo-sensitivity or are undergoing treatment for a photosensitive condition such as porphyria or lupus erythematosus,
6. Have received or are receiving chemotherapy for any type of cancer up to 90 days prior to the date of the baseline Imagio procedure,
7. Have previously participated in this registry,
8. Are currently enrolled in another investigational study or registry that would directly interfere with the current registry.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Medical products/devices used

Generic name:	Imagio
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-05-2018
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	NL63049.091.17