Improved diagnosis of clinically occult breast lesions

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To assess whether the use of RFIB instead of LCNB increases the probability of a definitive preoperative histological diagnosis in women with suspicious mammographic breast lesions. assess the *RFIB success rate*, defined as the proportion of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON38092

Source
ToetsingOnline

Brief title
IDOL

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast neoplasms; breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biopsy, breast, neoplasms, radiology

Outcome measures

Primary outcome

Histological diagnosis issued on the biopsy specimen and the surgical excision specimen, the number of cancelled procedures due to a contra-indication for RFIB and the number of unsuccessful RFIB procedures due to technical failure or a nonrepresentative biopsy sample.

Secondary outcome

A numerical pain score, procedure duration, cosmetic outcome and functional status post RFIB, complication rate, biopsy specimen quality and the chance of complete removal of a lesion.

Study description

Background summary

Each year, an increasing number of Dutch women are diagnosed with mammographically suspicious, nonpalpable breast lesions. The diagnostic work-up of these breast lesions has evolved from surgical excision biopsy to image guided, minimally invasive biopsy techniqueslarge core needle biopsy (LCNB) over the past decades. However, the current minimally invasive biopsy techniquesLCNB can not match the diagnostic accuracy of surgical excision biopsy yet because of problems such as underestimation of disease severity and unrepresentative sampling. As a result, LCNB is unable to provide a definitive preoperative diagnosis in up to 25% of patients.
In order to reduce this high proportion of women in whom a definitive preoperative diagnosis can not be established, radiofrequency-assisted intact specimen biopsy (RFIB) was introduced. Where LCNB retrieves some 4-8 small tissue fragments (2 x 20 mm), RFIB provides an intact (complete) biopsy specimen of intermediate (10-15 x 20 mm) size. Previous studies have reported substantial reductions in disease underestimation and unrepresentative sampling. Thus, the use of RFIB may lead to higher proportions of patients with

definitive preoperative diagnosis as compared to LCNB.

Study objective

To assess whether the use of RFIB instead of LCNB increases the probability of a definitive preoperative histological diagnosis in women with suspicious mammographic breast lesions. assess the *RFIB success rate*, defined as the proportion of patients in which the histopathological diagnosis issued on the RFIB specimen is equal to the final histopathological diagnosis. Secondary objectives are to evaluate patient*s experiences regarding pain and cosmetic outcome, adverse events and biopsy specimen quality.

Study design

Prospective cohort study.

Intervention

The studied diagnostic intervention is a vacuum assisted percutaneous intact biopsy of mammographically suspicious breast lesions under stereotactic mammographic guidance. The intervention will be performed using the FDA and CE approved IntactTM Breast Lesion Excision System.

Study burden and risks

RFIB will replace the standard biopsy procedure (LCNB) and thus does not burden the patient as an extra investigational procedure. Burdens that are associated with participation are a two-day delay in obtaining the biopsy result, because of additional processing steps that are needed to enable pathological assessment, and the time investment required for completing a questionnaire at 3 different time points. Additional risks associated with participation in the study are hypothetical and consist of an increased chance of non-specific biopsy related complications and burning of the skin.

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

- Female gender;
- Age >= 18 years;
- Nonpalpable mammographically suspicious breast lesion (classified as BIRADS 3-5) requiring stereotactic biopsy.

Exclusion criteria

- Legal incapability;
- Insufficient command of the Dutch language;
- Contraindication for temporarily stopping anticoagulant therapy;
- Inability to maintain a prone position for 1 hour;
- Ipsilateral breast implant;
- Lactation;
- Implanted electronic device;

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2011
Enrollment:	128
Type:	Actual

Medical products/devices used

Generic name:	Intact BLES - Breast Lesion Excision System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL35081.041.11