Feasibility study to assess the incremental value of DeclipseSPECT during radioactive seed localisation in breast cancer surgery.

Published: 06-11-2014
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Primary Objective: The primary objective of the present study is to assess the feasibility of using the declipseSPECT system for accurate I-125 seed localisations in breast cancer surgery.Secondary Objective(s): • Assess the accuracy of I-125 seed…

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

Summary

ID

NL-OMON40653

Source
ToetsingOnline

Brief title
Freehand-SPECT I-125 localisations for breast cancer surgery

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
Breast cancer, Breast tumour

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Eurostars project;Estar12115 Realtime

Intervention

Keyword: Freehand-SPECT, Radioactive seed localisation, RSL

Outcome measures

Primary outcome

Primary Objective: The primary objective of the present study is to assess the feasibility of using the declipseSPECT system for accurate I-125 seed localisations in breast cancer surgery.

• The outcome is a subjective opinion of the surgeon where it states that the declipseSPECT is useful or not for I-125 seed localisations and depth indications. This is scored by a 5-point scale.

Secondary outcome

Endpoint: Assess the accuracy of I-125 seed detection with freehand-SPECT compared to conventional gamma probe localisation.

• The outcome will be a distance in mm for the mismatch between the conventional gamma probe measurement and the freehand-SPECT localisation on the skin.

Endpoint: To determine if it is feasible to predict the accuracy of a tumour excision based on the location of the I-125 in the excision specimen.

• The outcome will be a measure for eccentricity of the I-125 in the specimen. The closest margin will be written down.

Study description

Background summary

Since 2008 we use in this institute, The Antoni van Leeuwenhoek Hospital, radioactive I-125 seeds for localisation of breast lesions. This technique is a replacement for the worldwide most used technique, the wire guided localisation. The wire guided localisation has several disadvantages for both the patient and the logistics.

Currently, the I-125 markers are localised with a gamma probe. This gamma probe gives an estimation of the distance from the probe to the I-125 by an acoustic noise. This signal is a 1D signal and requires expertise from the surgeon.

Since 2012, the NKI-AVL is in the possession of a (non invasive) freehandSPECT system (declipseSPECT) made possible by an European grand (Estar12115 Realtime). With this system we performed a study to examine the precision of this system for I-125 localisations (Pouw et al. 2014). This device is now used in standard clinical practice for I-125 markers at the nuclear medicine department.
The system is commercialised as an device to localise radioactive sources and has the relevant certification for this purpose. The device generates a 3D image of the I-125 seed in the tissue and simplifies the localisation by this manner. The declipseSPECT is also applied to localise other radioactive sources. During the procedure the location and the depth of the I-125 seed can be determined, which possibly enhances the accuracy and speed of the surgical procedure. An other advantage will be that the gamma probe of the declipseSPECT system acquires a 3D acquisition of the radioactivitydistribution and has thereby less problems of interference of compton scatter caused by Tc-99m.

A second step is immediately possible, with the same system an ex vivo scan of the specimen can be obtained to examine if the I125 seed is localised nicely in the centre of the tumour lump.

The hypothesis of this study is that the surgeon may be assisted by freehand-SPECT localisations of the I125 seed and thereby more accurate tumour excision will be accomplished. This may lead to improved quality of care for this specific patient group.

Study objective

Primary Objective: The primary objective of the present study is to assess the feasibility of using the declipseSPECT system for accurate I-125 seed localisations in breast cancer surgery.

Secondary Objective(s):
• Assess the accuracy of I-125 seed detection with freehand-SPECT compared to conventional gamma probe localisation.
• To determine if it is feasible to predict the accuracy of a tumour excision based on the location of the I-125 in the excision specimen.

Study design

Twenty patients scheduled for lumpectomy for breast cancer tumour excision undergo an additional 5-10 minutes I-125 seed localisation by freehandSPECT during surgery after localisation with the conventional gamma probe.

The location of the I-125 seed is marked on the skin after localisation with a gamma probe, directly after this localization a (non-invasive) freehand-SPECT-scan is performed and the concordance between the two measurements is written down. The difference is photographed.

The rest of the procedure is according to standard protocol where the excision takes place by guidance of the standard gamma probe. After excision another scan is made of the specimen at the operating room to assess the location of the I-125 seed within the specimen. The closest margin is written down.

For the surgeon and patient the whole surgical procedure is according to standard clinical protocol except for the additional freehand-SPECT scan. The surgeon evaluates after excision if the localisation with the two techniques was similar.

Study burden and risks

Participation does not impose any significant risks for patients or staff. The only thing changing is a delay of maximum 5-10 minutes in surgery time. This causes an extended time of narcosis with the known involved risks.

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

- Woman
- Age > 18
- Histological proven breast cancer
- I-125 seed at the right place in the tumour
- Scheduled for breast tumour lumpectomy by RSL
- Patients Provide writen *informed consent*

Exclusion criteria

- A pre-treated breast tumour.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	06-11-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL50466.031.14

Study results

Date completed:	27-05-2016
Actual enrolment:	20

Summary results

Trial is onging in other countries