Patient information combined for local therapy outcome assessment in bresast cancer.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Breast disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41193

Source
ToetsingOnline

Brief title
PICTURE BREAST - XS

Condition

- Breast disorders

Synonym
breast cancer, carcinoma of the breast

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: European Union Seventh Framework Programme for Research (FP7) grant

Intervention

Keyword: Breast, Cancer, Cosmetic, Outcome

Outcome measures

Primary outcome

The primary objective will be to create a reliable demonstrator (software) by integrating models of surgical techniques and treatment schemes, clinical patient data, multimodal imaging and individualised models of patient anatomy.

Secondary outcome

The secondary objective will be to assess the health related quality of life in the women who are participating in this study.

The information obtained from this study will be used in the creation of a demonstrator (personalised digital representation of a patient) by integrating models of surgical techniques and treatment schemes, clinical patient data, multimodal imaging and individualised models of patient anatomy.

The aim is to create a demonstrator that will be used as an aid to objective surgical planning, via simulation of the cosmetic effects of breast conserving surgery, as a decision support tool to communicate the available options to the patient and to enable standardised evaluation of the procedure.

Study description

Background summary

Breast cancer is the most common cancer to affect women in Europe, having a lifetime risk of 1 in 9. It is an increasingly treatable disease, and 10-year

survival now exceeds 80%. The primary treatment for breast cancer is surgery, which may be used in conjunction with adjuvant therapies, such as chemotherapy and radiotherapy. Given the high breast cancer survival rate, many women will live for many years with the potentially disfiguring aesthetic consequences of their surgical and therapeutic treatment. A good aesthetic outcome is an important endpoint for breast cancer treatment and is closely related to psychosocial recovery and quality of life.
When a woman faces a breast cancer diagnosis, and surgery is proposed, several options are available. The decision as to which type of surgery to offer patients is largely subjective and based almost exclusively on the judgment and experience of the clinician. The cosmetic outcome of surgery is a function of many factors including tumour size and location, the volume of the breast, its density, and the dose and distribution of radiotherapy. In breast-conserving surgery, there is evidence that approximately 30% of women receive a suboptimal or poor aesthetic outcome; however there is currently no standardised method of identifying these women.

Study objective

The PICTURE project aims to address these issues by providing objective tools, tailored to the individual patient, to predict the aesthetic outcome of local treatment. Using a combination of 3D photography and routinely acquired radiological images (i.e. mammography, ultrasound and MRI, when available), together with information about the tumour (size, location, shape etc.) we will develop techniques to biomechanically model the anatomy of the breast and the effect of surgical removal of cancerous tissue. This digital patient representation and associated predictive tools will enable alternative surgical strategies to be explored and the consequences of the available options, with respect to the appearance of the breast, to be visualised. This will aid communication with the patient of the type of breast surgery recommended by the surgeon, and will empower patients to take an active role in a shared decision making process.
The study will develop tools to enable the patient*s aesthetic appearance after treatment to be objectively evaluated. Current techniques use subjective methods, such as assessment by an expert panel, or computer analysis of 2-dimensional photography to estimate, for instance, breast asymmetry. By adopting recent developments in low cost 3D photography and depth sensing technology, we will develop a standardised, reproducible analysis tool which will base the aesthetic outcome evaluation on both the 3-dimensional shape of the reconstructed breast and its volume. This will establish standardised quality assurance and evaluation procedures, enabling institutions across Europe to be compared and factors that have a positive or negative impact on surgical outcome identified.
In summary, the demonstrator created by the PICTURE project will integrate models of surgical techniques and treatment schemes, clinical patient data, multi-modal imaging and individualised models of patient anatomy to build a personalised, digital representation of the patient. The aim is for this to be

used as an aid to surgical planning, via simulation of the cosmetic effects of breast conserving surgery, as a decision support tool to communicate the available options to the patient.

Study design

This is a cross-sectional study with no clinical interventions.

After providing written informed consent, each patient will be asked to:
1) Have her height, weight, bra and cup size recorded by a member of the clinical team.
2) Complete three questionnaires.
3) Have photographs taken of her unclothed torso (neck to navel) from various angles using several cameras, including a 3D camera.

This will complete the patient*s participation in the study.

Study burden and risks

After consent, each study patient will have photographs of her unclothed torso taken (from neck to navel) at various angles according to a pre-specified protocol. Height, weight and bra size will also be recorded at this time. In addition, the study patient will be asked to complete questionnaires. The estimated time taken for consent, photography and questionnaire completion is between two and three hours per subject.

We do not forsee any major risks or burdens for patients arising from this study.

However, some women may feel anxious when completing the questionnaires. A trained member of the study team will be available if the women wish to discuss any matters which concern them.

In addition, some women may feel uncomfortable having photographs taken of their breasts one year after surgery. This will be made clear to them during the consent process; and they will be free to withdraw from the study at any time, even in the photography studio.

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

Women who have undergone breast conserving surgery for early breast cancer more than one year ago.
Written informed consent obtained.

Exclusion criteria

Unable to provide written informed consent.
Younger than 18 years.
Benign breast disease.
Women who have had a mastectomy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-08-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL48954.058.14

Register	ID
Other	Volgt