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The influence of personality, anxiety and surgical treatment on quality of life in early stage breast cancer

Submission date 26/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 01/10/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR464

Study information

Scientific Title

Study objectives
The aim of this trial is to examine the role of patient personality on the relation between type of surgery and quality of life. It is hypothesised that breast cancer patients high on trait anxiety who get a breast conserving operation will subsequently have a lower Quality of Life (QoL) compared with high trait anxiety patients who receive a modified radical mastectomy, because they will worry about recurrence of cancer in the treated breast. The underlying goal is to provide women who may choose between a modified radical mastectomy and a breast conserving therapy advice concerning their decision.

One in every nine women in the Netherlands will develop breast cancer during her life. For early stage breast cancer, ablative therapy (being either a Modified Radical Mastectomy [MRM] or an ablation of the breast with a sentinel node procedure) and Breast Conserving Therapy (BCT) (i.e., a lumpectomy with an axillary lymph node dissection or a sentinel node procedure followed by radiotherapy) are comparable concerning overall survival. Disease-free survival is significantly shorter in patients with BCT, but recurrent cancer does not influence the overall survival. Due to early detection through screening programs and possibly by improved adjuvant treatment, for most patients breast cancer has become a chronic disease rather than a life threatening disease. Therefore, QoL is becoming increasingly important.

Hypothesis:
Patients with high scores on anxiety and neuroticism will experience a lower Quality of Life after breast conserving therapy compared to modified radical mastectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective, longitudinal preliminary study

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer, anxiety, neuroticism

Interventions
There will be no interventions in surgical treatment. Patients will choose surgical treatment together with their treating surgeon. This choice is based on international guidelines for early stage breast cancer and on personal preferences of the patient. Before diagnosis and one, three, six, 12 and 24 months after diagnosis, treatment patients will complete a set of questionnaires. These questionnaires will be the World Health Organisation Quality of Life questionnaire (WHOQOL-100), the State and Trait Anxiety Questionnaire (STAI), the Centre for Epidemiologic Studies Depression Scale (CES-D), the Fatigue Assessment Scale (FAS) and the Neuroticism Extraversion Openness Five-Factor Inventory (NEO-FFI) (only completed before diagnosis).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Quality of life over time in breast cancer patients
2. The influence of surgical treatment and personality

Secondary outcome measures
1. Quality of life over time in breast cancer patients compared to patients with a benign breast disease
2. The influence of personality

Overall study start date
01/09/2002

Completion date
01/01/2008

Eligibility

Key inclusion criteria
All women with a first event of a palpable lesion in the breast or an abnormal screening mammography.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
500

Key exclusion criteria
1. Breast cancer in the medical history
2. Dementia
3. T3 or T4 tumours
4. Unable to read or write Dutch

Date of first enrolment
01/09/2002

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
St. Elisabeth Hospital
Tilburg
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Sponsor information

Organisation
Tilburg University (The Netherlands)

Sponsor details
Faculty of Social and Behavioural Sciences
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Sponsor type
University/education

Website
http://www.tilburguniversity.nl/

ROR
https://ror.org/04b8v1s79

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Elisabeth Hospital (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration