

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
Registration date 26/02/2007	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 01/10/2008	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Prospective, longitudinal preliminary study

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

Netherlands

5000 LC

Sponsor information

Organisation

Tilburg University (The Netherlands)

ROR

<https://ror.org/04b8v1s79>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St. Elisabeth Hospital (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration