Introduction of a breast cancer care programme in ultra short stay (ambulatory/24 stay setting) in 4 early adopter centres: implementation and evaluation.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20135

Source
NTR

Brief title
MADO

Sponsors and support

Primary sponsor: ZonMw
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Intervention

Outcome measures

Primary outcome

Percent patients in ultra short stay,
- percent patients treated according to protocol,
- cost-effectiveness of the care programme and implementation programme.

Secondary outcome

1. Patient satisfaction;

2. Degree of involvement of home care nursing);

Process indicators:

a. access time to out patient department,

b. time spent in the diagnostic process,

c. access time to the surgical procedure,

d. surgical quality of care (complications, nr of re-operations),

e. patient satisfaction.

Study description

Background summary

Implementation objective(s) / Research question(s):

The aim of the knowledge transfer activities in this project is to inform relevant stakeholders about a set of interventions to support establishing a comprehensive care programme for breast cancer surgery in ultra short stay (the Univ Hosp Maastricht (uhM) breast cancer care programme).

Design:

Pre-post uncontrolled prospective trial.

Study population(s)/ Datasets:

All types of surgery for breast cancer patients of all ages.

Intervention to be implemented:

A comprehensive care programme for breast cancer surgery in ultra short stay; in 4 early adopter hospitals.

Implementation Activities/Strategy:

Implementation of the uhM breast cancer care programme will be put forward by a hospital-specific tailored implementation programme that will be adapted through the plan-do-study-act cycle, and that will be aimed at solving the barriers.
Tailored multifaceted implementation techniques, providing insight, inducing change and acceptance, and feed back to maintain the changes will be used

Outcome measures and Process idicators:

- Primary (percent patients in ultra short stay, percent patients treated according to protocol, cost-effectiveness of the care programme and implementation programme);
- Secondary (patient satisfaction, degree of involvement of home care nursing);

Process indicators (access time to out patient department, time spent in the diagnostic process, access time to the surgical procedure, surgical quality of care (complications, nr of re-operations), patient satisfaction).

Power/Data analysis:

Assuming the difference between the pre- and post-implementation period being 30% (uhM 71%) 40 patients are needed in each group to demonstrate statistical relevance with a power of 0.90.

Economic evaluation (if Applicable):

The cost-effectiveness of the programme (as compared to usual care, i.e. breast cancer surgery on an inpatient basis) will be calculated expressed as the incremental costs per Quality Adjusted Life Year (QALY).
The cost-effectiveness analysis will be performed from the societal perspective, with a time horizon of 6 weeks.

Time shedule:

Thirty six months total study length. Four phases:
1. inventory of existing care, preparation of implementation strategies 6 months; baseline measurement 6 months;

2. pilot implementation 6 months;
3. running of the comprehensive care programme 12 months;

4. evaluation, with consolidation 6 months.

Key words:

breast, cancer, surgery, ambulatory, implementation.

Study objective

There is no hypothesis in this implementation study, that is designed to record facilitating and inhibiting factors when an accepted and well functioning care programme is introduced in four early adopter hospitals.

Study design

N/A

Intervention

A comprehensive care programme for breast cancer surgery in ultra short stay; in 4 early adopter hospitals.

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Eligibility criteria

Inclusion criteria

Breast cancer patients of all ages undergoing all types of surgical interventions for breast cancer.

Exclusion criteria

Contraindications are those related to the physiology of the patient, and therefore not age or any of the surgery types employed in the treatment of breast cancer.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2004
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	15-09-2005
Application type:	First submission

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
NTR-new	NL467
NTR-old	NTR508
Other	: 945-14-411
ISRCTN	ISRCTN77253391

Study results

Summary results

N/A