

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20135

Bron

Nationaal Trial Register

Verkorte titel

MADO

Ondersteuning

Primaire sponsor: ZonMw

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percent patients in ultra short stay,
- percent patients treated according to protocol,

- cost-effectiveness of the care programme and implementation programme.

Toelichting onderzoek

Achtergrond van het onderzoek

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 indicators:

- 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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2004
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	15-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL467
NTR-old	NTR508
Ander register	: 945-14-411
ISRCTN	ISRCTN77253391

Resultaten

Samenvatting resultaten

N/A