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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/02/2007		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/02/2007	Completed	[X] Results		
Last Edited 28/05/2015	Condition category	[] Individual participant data		
Z0/U3/ZU13	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

945-14-411

Study information

Scientific Title

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

Acronym

MADO

Study objectives

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 University Hospital Maastricht (UHM) breast cancer care programme).

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the medical ethical committees of the initiating hospital (University Hospital Maastricht on the 7th December 2005 [ref: MEC 05-108]) and the other four hospitals:

- 1. Laurentius Hospital (ref: 05/11 PT/ SK 05/ 331) on the 6th December 2005
- 2. Orbis Medical Center (ref: 05.190/CS.EH) on the 28th October 2005
- 3. Leiden University Medical Center (ref: P05.111) on the 17th November 2005
- 4. St. Elisabeth Hospital (ref: 0536) on the 14th September 2005

Study design

Pre-post uncontrolled prospective trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Percent patients in ultra short stay:

- 1. Percent patients treated according to protocol
- 2. Cost-effectiveness of the care programme and implementation programme

Secondary outcome measures

- 1. Patient satisfaction
- 2. Degree of involvement of home care nursing)

Process indicators:

- 1. Access time to out patient department
- 2. Time spent in the diagnostic process
- 3. Access time to the surgical procedure
- 4. Surgical quality of care (complications, number of re-operations)
- 5. Patient satisfaction

Overall study start date

01/12/2004

Completion date

01/12/2007

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Key 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.

Date of first enrolment

01/12/2004

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre University Hospital Maastricht

Maastricht Netherlands 6202 AZ

Sponsor information

Organisation

University Hospital Maastricht (The Netherlands)

Sponsor details

Department of Surgery PO Box 5800 Maastricht Netherlands 6202 AZ

Sponsor type

Hospital/treatment centre

Website

http://www.unimaas.nl/default.asp?template=home. htm&fac=@fac@&nid=@nid@&id=niks&taal=en

ROR

https://ror.org/02d9ce178

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/07/2007		Yes	No
Results article	results	27/05/2015		Yes	No