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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
20/02/2007

Recruitment status
No longer recruiting

Registration date
20/02/2007

Overall study status
Completed

Last Edited
28/05/2015

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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

400

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