The Utrecht cohort for Multiple BREast cancer intervention studies and Long-term evaLuAtion

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To set up a cohort of breast cancer patients, collecting information on patient characteristics, short and long-term clinical and patient reported data, and to compare outcomes with a healthy refrence population. whichThe cohort will also serve as...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON54502

Source
ToetsingOnline

Brief title
UMBRELLA

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
Breastcancer, malignant breast tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Cohort multiple randomized controlled trial, Long-term evaluation, Quality of Life

Outcome measures

Primary outcome

Clinical parameters (e.g. co-morbidity, oncological history, symptoms, imaging,

technical and treatment data), clinical endpoints (e.g. toxicity, recurrence,

survival and side effects) and patient reported outcomes (e.g. Quality of Life

(QoL) and cosmetic evaluation).

Secondary outcome

Not applicable.

Study description

Background summary

Due to better treatment options and earlier detection, survival rates of patients with breast cancer continue to increase. As such, (late) treatment toxicity, (long-term) quality of life and cosmetic outcome are becoming more important. Also, many competing experimental interventions (e.g. treatment, lifestyle interventions) for breast cancer are being developed, all in need to be properly evaluated before being implemented in routine clinical care. Randomized Controlled Trials are the gold standard to do so, but they have shown many challenges, especially when applied in a cancer setting. The *cohort multiple Randomized Controlled Trial (cmRCT)* design is a promising design for multiple (simultaneous) randomized evaluations of experimental interventions, with potential for increased recruitment, comparability and long-term outcomes as a standard.

Study objective

To set up a cohort of breast cancer patients, collecting information on patient characteristics, short and long-term clinical and patient reported data, and to compare outcomes with a healthy refrence population. whichThe cohort will also serve as an infrastructure for efficient, fast and pragmatic randomized

evaluation of innovative interventions.

Study design

Observational, prospective cohort study, according to the *cohort multiple Randomised Controlled Trial* (cmRCT) design.

Study burden and risks

Patients will not experience direct benefit from participation in the UMBRELLA cohort. By participating, patients will contribute to the evidence on clinical and environmental factors associated with treatment outcome, QoL and survival. This will lead to better and a more personalized cancer care for future patients. Risks associated with participating in the UMBRELLA cohort study are negligible since it is an observational study. Filling out the questionnaires is the only burden for the patients participating in this cohort. It will take approximately 20 minutes to fill out the questionnaires each time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 years;
- Patients with breast cancer who undergo treatment in or are referred to the hospital;
- Informed consent - at least - for use of routinely collected clinical data.

Exclusion criteria

- Mentally incompetent patients;
- Inability to understand the Dutch language.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-07-2015
Enrollment:	19000
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-05-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-07-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-11-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-04-2020

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-02-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-11-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-10-2024
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL52651.041.15