Behavioral and psychosocial effects of rapid genetic counseling and testing in newly diagnosed breast cancer patients: a multicenter study.

No registrations found.

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

Summary

ID

NL-OMON20999

Source
Nationaal Trial Register

Brief title
TIME-trial (Timing In Mammacarcinoom Erfelijkheidsonderzoek-trial)

Health condition

breast cancer
borstkanker
erfelijkheidsonderzoek
genetic counseling and testing
rapid genetic counseling

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Ziekenhuis (Amsterdam)
and the University Medical Centre Utrecht
Source(s) of monetary or material Support: NutsOHRA Foundation

Intervention

Outcome measures

Primary outcome

- The choice of primary surgical treatment.

Secondary outcome

- Levels of perceived cancer risk

- Cancer worries

- Cancer-related distress

- Knowledge of genetic issues in breast cancer

- Satisfaction with treatment decisions

- Body image, sexuality

- Health-related quality of life

Study description

Background summary

In the Netherlands, approximately 12,000 women are diagnosed with breast cancer annually, of whom about 5-10% carry a mutation in the BRCA1 or BRCA2 gene. Genetic counseling and DNA testing are usually offered to selected patients after primary treatment has been completed (e.g. the first year after diagnosis). For women with a mutation in one of the two breast-ovarian cancer syndrome genes, chances of a second breast cancer are high, and therefore a proportion of these women may opt for preventive measures in addition to their immediate breast cancer treatment. Contralateral prophylactic mastectomy significantly reduces this risk, and is associated with a reduction in mortality. Genetic counseling and testing for breast cancer typically takes approximately 4-6 months to complete.
However, some hospitals and laboratories are now able to generate test results within 3 to 6 weeks. This technology of rapid genetic testing creates new opportunities for providing both women and their treating surgeons with information potentially relevant for deciding between available treatment options, including type of surgery and adjuvant therapy.

The study will focus on newly diagnosed breast cancer patients who, prior to receiving

treatment, are identified as having at least a 10% risk of carrying a mutation in the BRCA1 or BRCA2 genes.
We will investigate whether women with a recent diagnosis of breast cancer make use of rapid genetic counseling when offered.
Furthermore, we will investigate whether the process of genetic counseling (and subsequent DNA testing) has influence on the choice of treatment, and whether and how such rapid genetic counseling and testing (RGCT) affects levels of risk perception, cancer-related worries and distress, and decisional satisfaction.

This multicenter study will employ a randomized controlled trial. In an 18 month period newly diagnosed breast cancer patients will be recruited from 13 hospitals in the Amsterdam and Utrecht regions of the Netherlands. Eligible patients will be randomized either to the “usual care” (UC) arm of the study, or to the RGCT arm of the study. The randomization will be done in a ratio of 1:2

Women in the RGCT arm of the study will be referred for genetic counseling within a week after diagnosis, prior to the primary surgery.

Women in the UC condition will receive standard advice and care from their treating physician.

Standardized questionnaires will be administered to all patients at study entry, and at 6 and 12 months to assess all psychosocial outcomes. The endpoints will include:
(1) the choice of clinical management strategy, including the uptake of direct bilateral mastectomy (BLM) or of delayed preventive contralateral mastectomy (PCM);
(2) cancer risk perception, cancer-related worry and distress;
(3) knowledge of genetic aspects of breast cancer;
(4) decisional satisfaction; and
(5) health-related quality of life (HRQL).
The study will also evaluate women’s experience of and satisfaction with RGCT (i.e., the timing and quality of the services provided, the perceived impact on treatment decisions, perceived need for additional psychosocial services, etc.). Data on surgical outcomes will be abstracted from the medical records. A subset of women will be interviewed to obtain supplementary, qualitative data about the RGCT experience.

This study will provide essential information about the impact of RGCT on the choice of primary surgical treatment among women with breast cancer with an increased risk that their cancer has a hereditary basis, and about the psychosocial effects of the RGCT process and the ensuing treatment decisions. It will inform clinical geneticists, surgeons and patients

about the potential benefits and risks of RGCT, and will be useful in further shaping the content and process of genetic counseling in the diagnostic and early treatment phase of breast cancer.

The study will also yield recommendations for improving the quality of the multidisciplinary care provided in breast cancer clinics by the addition of genetic expertise when patients are at relatively high risk of having a genetic predisposition for breast cancer.

Study objective

It is expected that women with a BRCA gene mutation more often will opt for a bilateral mastectomy or a delayed contralateral mastectomy than women without such a mutation.

It is expected that women with a BRCA gene mutation more often prefer a mastectomy instead of breast conserving therapy.

Study design

Data will be collected at three points in time:

- within a few days after diagnosis

- after 6 months

- after 12 months

Intervention

The intervention group will be offered rapid genetic counseling and testing.

The control group will receive usual care, and will be offered genetic counseling and testing after their primary treatment.
Although rapid genetic counseling and testing is also available in the usual care setting, it is rarely used.

Contacts

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Eligibility criteria

Inclusion criteria

1. Women with a clinically confirmed, newly diagnosed primary breast cancer who meet the criteria for referral for genetic counseling and possible DNA analysis.

Exclusion criteria

1. Age < 18 years

2. Doesn't speak Dutch

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2008
Enrollment:	255
Type:	Actual

Ethics review

Positive opinion

Date:	14-10-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32689
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1432
NTR-old	NTR1493
CCMO	NL24252.018.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON32689

Study results

Summary results
N/A