FOCUS: Future Of Cancer Genetic testing as Usual and Standard care – breast cancer study

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24872

Source
NTR

Brief title
FOCUS - breast cancer study

Health condition

breast cancer

Sponsors and support

Primary sponsor: University Medical Center Utrecht, department of Genetics
Source(s) of monetary or material Support: University Medical Center Utrecht: department of genetics, and partially funded by Pfizer, AstraZeneca,

Intervention

Outcome measures

Primary outcome

acceptability and feasibility for healthcare professionals and patients of a mainstream genetic testing pathway.

Secondary outcome

uptake of genetic testing

Study description

Background summary

Genetic testing for breast cancer patients may have clinical implications and lead to different treatment options (e.g. surgical treatment, but also systemic and radiotherapeutic treatment). The criteria for germline genetic testing are expected to expand in the coming years, meaning that even larger numbers of patients will be eligible for genetic testing. Because of the possible treatment implications of genetic test results, it is important to offer this test to eligible patients soon after a cancer diagnosis. In addition, germline genetic test results are important for prevention or early detection of a second primary cancer, both for the patient and for healthy family members who are also carriers. Despite the importance of genetic testing, research has shown that significant numbers of eligible cancer patients are currently not referred to a genetics department. This has led to several initiatives to improve the uptake of genetic testing.
Mainstreaming of germline genetic testing is the integration of this testing into the routine care of patients with cancer. The aim of mainstreaming is to enable non-geneticist cancer specialists to offer a genetic test to all eligible patients in an early stage after diagnosis.
A mainstream pathway has been developed and implemented in nine hospitals in the Netherlands, including an obligatory training module to prepare non-genetic healthcare professionals to offer adequate pre-test counseling for patients with breast cancer.
The aim of this study is to evaluate if this new mainstreaming pathway is feasible and acceptable to patients and healthcare professionals, and provides a good quality of care.

Study objective

mainstreaming of germline genetic tests in regular healthcare is feasible for non-genetic healthcare professionals and acceptable for both patients and healthcare professionals

Study design

Questionnaires patients:
first questionnaire directly after pre-test counseling of genetic test by non-genetic healthcare professional or clinical geneticists/genetic counselor. Second questionnaire approximately four weeks after patients received their genetic test result.
Questionnaires healthcare professionals:
First questionnaire before completing the online training module, second and third questionnaire, respectively three and six months after working according to the mainstream genetic testing pathway.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with (history of) breast cancer and eligible for genetic testing
2. Intervention group: pre-test counseling for germline genetic testing is performed by non-genetic healthcare professional
3. Control group: pre-test counseling for germline genetic testing is performed by genetic healthcare professional.

Exclusion criteria

1. Patients that receive genetic counseling for predictive genetic testing
2. Unable to understand, speak and write Dutch language
3. For control group: patients that received genetic testing in the past and are eligible for testing of additional genes.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2019
Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9712
Other	METC Utrecht : 19-526/C

Study results