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

Gepubliceerd: 02-09-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24872

Bron
NTR

Verkorte titel
FOCUS - breast cancer study

Aandoening

breast cancer

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, department of Genetics
Overige ondersteuning: University Medical Center Utrecht: department of genetics, and partially funded by Pfizer, AstraZeneca,

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Contactpersonen

Publiek

University Medical Center Utrecht
Kyra Bokkers

0887553800

Wetenschappelijk

University Medical Center Utrecht
Kyra Bokkers

0887553800

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2019
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9712
Ander register	METC Utrecht : 19-526/C

Resultaten