DNA testing for BRCA1/2 in breast cancer patients prior to genetic counseling: DNA-direct

Published: 21-06-2011
Last updated: 15-05-2024

Optimalisation of genetic counseling for patients with breast cancer, by also making use of other ways to provide information than the personal consultation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational non invasive

Summary

ID

NL-OMON35994

Source
ToetsingOnline

Brief title
DNA-direct

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
BRCA gene mutation, hereditary breast cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: BRCA, Breast cancer, DNA testing, Genetic counseling

Outcome measures

Primary outcome

Satisfaction of the patient regarding genetic testing and counseling

Psychological / psychosocial burden of the patient regarding genetic testing

and counseling

Secondary outcome

Factors that determine the patient*s choice for or against the DNA-direct

procedure

Waiting and processing times

Family characteristics of detected families with a mutation or a so-called

unclassified variant type 3 (UV-III) in the BRCA1 or BRCA2 gene

Study description

Background summary

It is customary for breast cancer patients who are referred to Human Genetics for genetic advice, to receive a consultation with a genetic counselor both prior to as following the results of DNA-testing. In this first consultation, information regarding the chances and (im)possibilities of DNA-testing is discussed, before DNA-testing for a mutation in the BRCA1 or BRCA2 genes is started. This information is for the most part generic. A consultation prior to DNA-testing is sometimes perceived as a delaying factor by breast cancer patients and/or their referring doctors, due to the result of DNA-testing being required for personal genetic advice. It is also known that patient recall for oral medical information is generally low.

We want to evaluate the effects of replacing the first consultation by information provided by telephone plus written and digital form with a movie and website (DNA-direct procedure) on the experience and psychosocial burden of

breast cancer patients, as well as the speed and quality of genetic advice. This will be compared to the current procedure where oral information is provided during a consultation before DNA-testing (DNA-intake procedure).

Study objective

Optimalisation of genetic counseling for patients with breast cancer, by also making use of other ways to provide information than the personal consultation.

Study design

150 patients who are or have been in treatment for breast cancer and were referred for genetic counseling, may choose whether to have a personal consultation or information by telephone and written/digital form, prior to DNA testing. All patients receive the same questionnaires when included (baseline) and after the result of genetic counseling (outcome). A small selection of these patients, namely 1) those who carry a mutation in the BRCA1 or BRCA2 gene, or 2) patients who report problems with the procedure, as well as 3) patients chosen by random selection (n=10), then receive an invitation for a 30 minute long semistructured interview by telephone. The expected total of interviewees is 30 of 150 patients.

Study burden and risks

Time investment in order to fill in 2 questionnaires (20 minutes per questionnaire) and for 30 of 150 patients (20%) to be interviewed once (30 minutes).

Contacts

Public
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500HB
NL
Scientific
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All female breast cancer patients (recently diagnosed or in the past) referred to Human Genetics of the Radboud University Medical Centre Nijmegen for genetic counseling.

Exclusion criteria

For the DNA-direct procedure: problems with (large amounts of) written Dutch text, current psychological / psychiatric treatment (including medication), problems with family communication about cancer as estimated by the patient.

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:	Recruitment stopped
Start date (anticipated):	12-08-2011
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	21-06-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22096
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL36219.091.11
OMON	NL-OMON22096