Feasibility ex vivo Homologous Recombination Deficiency (HRD) test in advanced breast cancer disease: a pilot study

Gepubliceerd: 20-11-2015 Laatst bijgewerkt: 18-08-2022

This study will investigate the feasibility of HRD test in metastatic lesions of different sites among breast cancer patients who will start treatment with chemotherapy. The sites of metastatic lesions that will be investigated are: liver, lymph…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24673

Bron
Nationaal Trial Register

Verkorte titel
ex vivo HRD test

Aandoening

Defective homologous recombination DNA repair imposed by BRCA1 or BRCA2 gene deficiencies sensitizes cells to double strand break (DSB)-inducing DNA damaging agents like platinum derivates and anthracyclines. The formation of RAD51 IRIF is impaired in BRCA1 or BRCA2 defective cells and also in other genetic defects leading to HR deficiency. In current healthcare these anti-cancer agents e.g. platinum derivates are usually administered at late stage of advanced breast cancer from which only a subpopulation of patients benefit from the treatment. Having a test that can predict whether or not an individual patient could benefit from the treatment will provide the option to provide the treatment at an earlier stage of the disease.

Ondersteuning

Primaire sponsor: Erasmus MC, Cancer Institute, department of Medical Oncology, Rotterdam.
Overige ondersteuning: Alpe d'Huzes KWF funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

the proportion of patients with a useful test result (Putest)
will be considered as the primary end point

Toelichting onderzoek

Doel van het onderzoek

This study will investigate the feasibility of HRD test in metastatic lesions of different sites among breast cancer patients who will start treatment with chemotherapy. The sites of metastatic lesions that will be investigated are: liver, lymph nodes, and subcutaneous lesions.

Onderzoeksopzet

na

Onderzoeksproduct en/of interventie

na

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• The site of the tumor should be amendable for biopsy. NB lung metastases (high risk of hematothorax) and bone metastases (not suitable for ex vivo test because calcifications interfere with experimental procedures) are excluded.

• Age >18 years

• WHO performance status 0 or 1

• Bilirubin <1.5 ULN and both AST and ALT <2,5x ULN in case a liver biopsy is planned

• Platelets > 100 x 10e9/L

• INR <1.5

• Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Current therapeutically use of anti-coagulant (coumarin derivates, warfarin, heparin or low molecular weight heparin [LMWH]) whereby a short interruption of drug use is not allowed. LMWH if used for prophylaxis is allowed.

• Any psychological condition potentially hampering compliance with the study protocol

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	13-02-2015
Aantal proefpersonen:	0
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-11-2015
Soort:	Eerste indiening

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	NL5447
NTR-old	NTR5574
Ander register	Erasmus Medisch Centrum : MEC14-295

Resultaten