ex vivo assessment of Repair Capacity (RECAP) in advanced breast cancer patients (extension of the HRD pilot study)

Gepubliceerd: 05-07-2017 Laatst bijgewerkt: 18-08-2022

This study will investigate whether within BR grade 3 ER/PR+ or HER2+ breast cancers the percentage of homologous recombination deficiency is substantially higher in metastatic lesions compared to primary breast cancers.

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

Samenvatting

ID

NL-OMON28235

Bron
Nationaal Trial Register

Verkorte titel
RECAP

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: Erasmus Medisch Centrum
Overige ondersteuning: Alpe d'Huzes foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The percentage of biopsies from local recurrent or metastatic lesions showing HRD among patients with BR grade 3 ER/PR+ or HER2+ breast cancer.

Toelichting onderzoek

Achtergrond van het onderzoek

The ex vivo assessment of Repair Capacity (RECAP) test in advanced breast cancer patients is an extension of the HRD pilot study. In previous studies we have investigated percentages of homologous recombination deficient (HRD) tumors on primary tumor samples as well as on biopsies of metastatic lesions within all subtypes of breast cancer. We observed that within the TNBC the percentage of HRD tumors was more or less similar in primary and metastatic breast cancer. Whereas, we found that within the BR grade 3 ER/PR+ or HER2+ breast cancers the percentage of HRD was higher in the metastatic lesions compared to another cohort of primary breast cancers. It is of the utmost importance to determine whether these observations are maintained when the HRD test is performed on more metastatic breast cancer patients. Therefore, we want to enlarge the group of BR grade 3 ER/PR+ metastatic breast cancers to prove that within the BR grade 3 ER/PR+ breast cancers the percentage of HRD is indeed significantly increased in the metastatic lesions compared to primary breast cancers. This could have great clinical implications, in terms of prognosis as well as therapeutically.

Doel van het onderzoek

This study will investigate whether within BR grade 3 ER/PR+ or HER2+ breast cancers the percentage of homologous recombination deficiency is substantially higher in metastatic lesions compared to primary breast cancers.

Onderzoeksopzet

na

Onderzoeksproduct en/of interventie

na

Contactpersonen

Publiek

Erasmus MC, Room 471

A. Jager
Groene Hilledijk 301

Rotterdam 3075 EA
The Netherlands
Tel 010 704 17 33

Wetenschappelijk

Erasmus MC, Room 471

A. Jager
Groene Hilledijk 301

Rotterdam 3075 EA
The Netherlands
Tel 010 704 17 33

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Breast cancer patients with local recurrent or distant metastases

- The site of the tumor should be easy amendable for biopsy. NB: lung metastases (high risk of hematothorax) and bone metastases (not suitable for ex vivo HRD 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 <5x ULN in case a liver biopsy is planned

- Platelets >100 x 10e9/L and INR <1.5, unless platelet/INR values are not necessary

according to local protocols or after consent of the intervention radiologist for that particular site of biopsy (e.g. biopsy of the skin).

- 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. Use of low molecular weight heparin (LMWH) should be interrupted shortly before biopsy is scheduled, unless this is not necessary according to local protocols or after consent of the intervention radiologist.

- 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

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-06-2017
Aantal proefpersonen:	44
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-07-2017

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	NL6376
NTR-old	NTR6560
Ander register	: MEC17-213 Erasmus Medisch Centrum

Resultaten