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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28235

Source
Nationaal Trial Register

Brief title
RECAP

Health condition

Breast cancer

Sponsors and support

Primary sponsor: Erasmus Medisch Centrum
Source(s) of monetary or material Support: Alpe d'Huzes foundation

Intervention

Outcome measures

Primary outcome

The percentage of biopsies from local recurrent or metastatic lesions showing HRD among

patients with BR grade 3 ER/PR+ or HER2+ breast cancer.

Secondary outcome

- The percentage of biopsies from local recurrent or metastatic lesions showing HRD among the BR grade 3 ER/PR+ subgroup alone.

- The percentage of biopsies from local recurrent or metastatic lesions showing HRD among patients with BR grade grade 1/2 ER/PR+ breast cancers and TNBC.

Study description

Background summary

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.

Study objective

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.

Study design

na

Intervention

na

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

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

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-06-2017
Enrollment:	44
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-07-2017
Application type:	First submission

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	NL6376
NTR-old	NTR6560
Other	: MEC17-213 Erasmus Medisch Centrum

Study results