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

No registrations found.

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

Summary

ID

NL-OMON24673

Source
NTR

Brief title
ex vivo HRD test

Health condition

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.

Sponsors and support

Primary sponsor: Erasmus MC, Cancer Institute, department of Medical Oncology, Rotterdam.
Source(s) of monetary or material Support: Alpe d'Huzes KWF funding

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

na

Study description

Study objective

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.

Study design

na

Intervention

na

Contacts

Public
Erasmus MC, Room 471

A. Jager
Groene Hilledijk 301

Rotterdam 3075 EA
The Netherlands

Tel 010 704 17 33
Scientific
Erasmus MC, Room 471

A. Jager
Groene Hilledijk 301

Rotterdam 3075 EA
The Netherlands
Tel 010 704 17 33

Eligibility criteria

Inclusion criteria

• 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

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.

• 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
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2015
Enrollment:	0
Type:	Actual

Ethics review

Positive opinion

Date:	20-11-2015
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	NL5447
NTR-old	NTR5574
Other	Erasmus Medisch Centrum : MEC14-295

Study results