In vivo REsponse evaluation of colorectal liver metastases during systemic therapy using optical SPECTroscopy techniques

No registrations found.

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

Summary

ID

NL-OMON22669

Source
Nationaal Trial Register

Brief title
RESPECT

Health condition

unresectable colorectal liver metastases

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips

Intervention

Outcome measures

Primary outcome

The aim of this pilot study is to investigate whether chemotherapy response can be detected with optical spectroscopy (diffuse reflectance and fluorescence spectroscopy) in patients with unresectable colorectal liver metastases receiving first line systemic therapy.

Secondary outcome

1. To compare the accuracy of chemotherapy response using optical spectroscopy with standardized RECIST criteria;

2. To correlate spectroscopic measurements with tissue characteristics from biopsies;

3. During the measurement procedure, possible improvements to the measurement hardware will be recorded which can provide information for possible alterations of hardware design for improved clinical applicability in the future.

Study description

Background summary

Response monitoring of patients undergoing systemic therapy for colorectal liver metastases in the era of new targeted drugs is troublesome and the development of new monitoring tools is needed. The primary aim of this pilot study is to investigate whether chemotherapy response can be detected with optical spectroscopy in patients with unresectable colorectal liver metastases receiving first line systemic therapy. Optical spectroscopy measurements will be acquired from normal liver tissue and the liver metastasis; a biopsy will also be taken. This will be done prior to the start of systemic therapy and at the first response monitoring moment.

The Percuspect study is extended to breast cancer patients. 36 additional patients with this condition will be included. METC of NKI approved this modification per April 25, 2013.

Study objective

The aim of this pilot study is to investigate whether chemotherapy response can be detected with optical spectroscopy (diffuse reflectance and fluorescence spectroscopy) in patients with unresectable colorectal liver metastases receiving first line systemic therapy.

Study design

Day 0 and day of first response monitoring

Intervention

Histological biopsy procedure (standard core biopsy procedure) - before and after stardard of care chemotherapy.

Contacts

Public

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Eligibility criteria

Inclusion criteria

1. Patients with unresectable colorectal liver metastases;

2. The liver lesions are safely accessible according to an intervention-radiologist;

3. First line systemic treatment with Capacitabin and Oxaliplatin or FOLFOX, both with or without biologicals;

4. Written informed consent >18y.

Breast Specific Inclusion criteria
- Breast patients with a BIRADS score 4 or 5

Exclusion criteria

1. Patients with suspected sensitivity to light; e.g. patients who have had photodynamic therapy;

2. Patients with bleeding disorders (such as hemophilia) or bleeding complications from biopsies, dental procedures or surgery;

3. Patients using any anti-coagulant medication at the time of biopsy: all aspirin derivatives, coumarines, platelet function inhibitors, heparins (including LMWHs) and oral factor Xa inhibitors are not allowed, unless medication can either be safely stopped or counteracted;

4. Patients with indequate hematology and coagulation status as measured by:

* Hb < 6.0 mmol/L;

* Platelet count < 100 x 109/L;

* PT < 1.5 x Upper limit of normal (ULN);

* APTT < 1.5 x ULN;

* PT-INR < 1.5 on the day of biopsy in patients using coumarines;

* Patients known with contraindications for lidocaine (or its derivatives).

Breast Specific Exclusion criteria
- Patients who have a history of breast cancer and/or who have received prior chemotherapy, endocrine therapy, or radiation therapy

- Patients who have breast implants

- Patients needing a stereotactic breast biopsy (i.e. non palpable-, ultrasound opaque lesions).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	21-06-2013
Enrollment:	22
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-06-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38470
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3838
NTR-old	NTR4026
CCMO	NL42902.031.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38470

Study results

Summary results
N/A