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

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

Samenvatting

ID

NL-OMON22669

Bron
Nationaal Trial Register

Verkorte titel
RESPECT

Aandoening

unresectable colorectal liver metastases

Ondersteuning

Primaire sponsor: Philips Research
Overige ondersteuning: Philips

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Day 0 and day of first response monitoring

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

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 nog niet gestart
(Verwachte) startdatum:	21-06-2013
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-06-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38470
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A