The OCEANS trial: fluorescence guided surgery with methylene blue for better visualization of small intestine neuroendocrine tumors: a feasibility study.

Gepubliceerd: 05-03-2021 Laatst bijgewerkt: 18-08-2022

Visualization of small intestine neuroendocrine tumors with methylene blue and near-infrared fluorescence imaging is feasible.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24327

Bron
NTR

Verkorte titel
The OCEANS trial

Aandoening

Small intestine neuroendocrine tumors (SI-NET)

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The in-vivo tumor to background ratio (TBR) of the primary tumor.

Toelichting onderzoek

Achtergrond van het onderzoek

Neuroendocrine tumors of the small intestine (SI-NET) are rare tumors. Patients often do not present until distant metastases are already present in the abdomen. Curative surgery is no longer possible for these patients. The clinical problem is that it is often difficult to diagnose these distant metastases. For this reason, the guidelines state to operate with a laparotomy and then palpate and visualize the entire abdominal cavity. It is common for a patient to undergo a laparotomy, after which it becomes clear that distant metastases are present. It is decided not to continue the operation.
The aim of this study is to investigate whether a combination of intravenous methylene blue and fluorescence imaging can visualize neuroendocrine tumors. If this is possible, in the future it can be assessed with fluorescence by means of laparoscopy whether distant metastases are present in the abdomen. In this way, a group of patients can be sparred from an unnecessary laparotomy. Moreover occult metastases can be identified for resection when curation is possible.

Doel van het onderzoek

Visualization of small intestine neuroendocrine tumors with methylene blue and near-infrared fluorescence imaging is feasible.

Onderzoeksopzet

Patient participation ends immediately after surgery.

Onderzoeksproduct en/of interventie

Patients receive an intravenous injection of methylene blue (0.5 - 1.0 mg/kg) during surgery after which near-infrared fluorescence imaging will be performed.

Contactpersonen

Publiek

Erasmus MC
Hidde Galema

0107042125

Wetenschappelijk

Erasmus MC
Hidde Galema

0107042125

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria
- Patients with lesions on the Galium-68-dotatate PET/CT scan suspected for a Small intestine Neuro-endocrine tumor (SI-NET);
OR
- Patients with biopsy proven SI-NET;

AND
- With the primary SI-NET in situ
- ≥ 18 years of age;
- Before patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients taking the following medication 30 days or less prior to surgery: selective serotonin reuptake inhibitors (SSRI’s), serotoninnoradrenalin reuptake inhibitors (SNRI’s), tricyclic antidepressants (TCA’s), bupropion, or buspiron.
- Use of serotonergic party drugs (MDMA, ecstasy, GHB, cocaine) 30 days or less prior to surgery.
- Patients diagnosed with Glucose-6-Phosphate Dehydrogenase (G6DP) deficiency;
- Patients with a clinical significant history of allergic reaction to MB
- Patients who are pregnant or breastfeeding, female from childbearing potential without

adequate contraceptives.
- Incapacitated subjects.
- Any condition that the investigator, surgeon or anaesthesiologist considers to be potentially jeopardizing the patient’s well-being or thestudy objectives.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-03-2021
Aantal proefpersonen:	17
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:	05-03-2021
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	NL9305
Ander register	METC Erasmus Medical Centre : MEC-2021-0021

Resultaten