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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24327

Source
NTR

Brief title
The OCEANS trial

Health condition

Small intestine neuroendocrine tumors (SI-NET)

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The TBR of (lymph node) metastases
The number of occult lesions found
The optimal dose of MB
The optimal time frame for the administration of MB
Determine confirmation of your signal with fluorescence microscopy

Study description

Background summary

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.

Study objective

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

Study design

Patient participation ends immediately after surgery.

Intervention

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.

Contacts

Public
Erasmus MC
Hidde Galema

0107042125
Scientific
Erasmus MC
Hidde Galema

0107042125

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-03-2021
Enrollment:	17
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-03-2021
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	NL9305
Other	METC Erasmus Medical Centre : MEC-2021-0021

Study results