Tumour-specific fluorescence-guided surgery for gastroenteropancreatic neuroendocrine neoplasms using PHT001: a phase 1, open-label, single-arm, dose-escalation study

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MMC(IRDye800CW)-TOC is safe to inject in patients for intraoperative visualization of gastroenteropancreatic neuroendocrine neoplasms

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26268

Bron
NTR

Verkorte titel
PHOTON

Aandoening

Gastroenteropancreatic neuroendocrine neoplasms

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Cancer Center Amsterdam, Amsterdam Gastroenterology Endocrinology Metabolism

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. No. of (serious) adverse events and suspected unexpected serious adverse reactions;
2. Identify the dose with the optimal tumour-to-background ratio;
3. Ex vivo validation of targeted uptake by tumour tissue by histopathology.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Currently, preoperative imaging of GEP-NENs is conducted using 68Ga-DOTATATE, which makes use of the overexpressed somatostatin type 2 receptors (SSTR-2) on cell surfaces of GEP-NENs. PHT001 is proved to be able to clearly delineate tumour boundaries in vitro on human biospecimens of NENs. Successful implementation PHT001 in clinical practice is therefore expected to aid in adequate and complete removal of tumour cells, identify malignant lymph nodes and distant metastases.

Objective: The aim of this study is to produce and implement a SSTR-2 targeted fluorescent tracer and assess its safety and best dose to accurately identify gastroenteropancreatic neuroendocrine neoplasms during surgical resection.

Study design: Phase 0 microdosing study.

Study population: Patients undergoing surgery for GEP-NEN.

Intervention: Patients will receive a bolus injection of MMC(IRDye800CW)-TOC.

Main study end-points:
• No. of (serious) adverse events and suspected unexpected serious adverse reactions;
• Identify the dose with the optimal tumour-to-background ratio;
• Ex vivo validation of targeted uptake by tumour tissue by histopathology.

Doel van het onderzoek

MMC(IRDye800CW)-TOC is safe to inject in patients for intraoperative visualization of gastroenteropancreatic neuroendocrine neoplasms

Onderzoeksopzet

Primary outcomes:
1. SAEs will be assessed within 30 days after administration of the IMP, and will be graded according to CTCAR v5.0;
2. Optimal dose will be assessed after acquiring and analyses of images using ImageJ software;
3. Ex vivo validation will be assessed by comparing tissue slides with H&E, anti-SSTR2 and fluorescence microscopy using the Nikon Ti2 microscope or Odyssey CLx device.

Secondary outcomes:
1. Comparison of new lesions will be made postoperatively by correlating intraoperative finding with the pre-operative PET-CT images;
2. Complete removal of tumour tissue will be assessed by the pathologist postoperatively.

The overall follow-up period is 30 days.

Onderzoeksproduct en/of interventie

Single bolus injection of PHT001

Contactpersonen

Publiek

Amsterdam UMC
Enes Kacmaz

020-5669111

Wetenschappelijk

Amsterdam UMC
Enes Kacmaz

020-5669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients undergoing surgery for a primary GEP-NEN (stomach, duodenum, ampulla of Vater,

pancreas, jejunum, ileum, colon or rectum), of any stage, grade and intent (i.e. curative/palliative) or metastases of a GEP-NEN;
• SSTR-2 positive disease, as proven by a DOTATATE PET scan pre-operatively (conducted at location AMC and part of standard care);
• Age of 18 years and older;
• Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• NEN, not meeting the inclusion criteria (non-GEP-NEN, unknown location);
• Pregnant or breast-feeding women;
• Known hypersensitivity to the investigational medicinal product (IMP) or any of its components;
• Patients with an allergic/infusion reaction to 1 mg of TOC test dose of the unlabelled TOC;
• Patients with known allergies to intravenous radiographic contrast agents;
• Patients who have not provided a signed informed consent form to participate in the study, prior to the start of any protocol related activities;
• Patients who, within the last 30 days, have participated in any clinical study of a therapeutic agent which may interfere with the safety or efficacy analysis of the IMP;
• Serious non-malignant disease (e.g. psychiatric infectious, autoimmune, metabolic, renal, hepatic, cardiovascular or hematological), that may interfere with the objectives of the study or with the safety of the subject, as judged by the investigator;
• A marked baseline prolongation of QT/QTc interval (e.g., repeated demonstration of a QTc interval >450 ms);
• A history of additional risk factors for torsade de pointes (e.g., heart failure, hypokalaemia, family history of Long QT Syndrome);
• The use of concomitant medications that prolong the QT/QTc interval.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
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:	01-04-2022
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9298
Ander register	METC AMC : Pending

Resultaten