

Improving Treatment Options for Somatostatin Type 2 Receptor Negative Neuroendocrine Tumor Patients

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The combined treatment with the epigenetic drugs valproic acid and hydralazine will lead to an increase in SSTR2 expression levels in patients with metastasized Grade 1 or 2 NETs with low uptake on 68Ga-DOTATATE-PET CT.

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

Samenvatting

ID

NL-OMON23147

Bron

Nationaal Trial Register

Verkorte titel

IMPROVE-NET

Aandoening

metastasized neuroendocrine tumors (NETs)

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam, the Netherlands

Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint will be the percentage of patients that will have an uptake of 68Ga-DOTATATE in the tumor equal to or above that of the liver after the 14 days treatment period.

Toelichting onderzoek

Achtergrond van het onderzoek

Somatostatin receptor type 2 (SSTR2) expressions are of eminent importance for the staging and treatment of neuroendocrine tumors (NETs). The clinical benefit obtained by treatment with unlabeled and radiolabeled somatostatin analogues does not apply to the subset of patients with SSTR2-negative tumors. The lack of these anti-tumoral options could be responsible for the inferior outcome of these patients compared to those with SSTR2-positive tumors. Recent in vitro data showed the possibility of upregulating SSTR2 expression in pancreatic NET cells through treatment with epigenetic drugs. Translating these methods into clinic could substantially improve diagnostic and treatment options for SSTR2-negative tumors.

The aim of this prospective proof-of-concept study is to increase the expression of the SSTR2 in SSTR2-negative NET patients to levels amenable for somatostatin analogue treatment through the use of epigenetic drugs.

Doel van het onderzoek

The combined treatment with the epigenetic drugs valproic acid and hydralazine will lead to an increase in SSTR2 expression levels in patients with metastasized Grade 1 or 2 NETs with low uptake on 68Ga-DOTATATE-PET CT.

Onderzoeksopzet

Baseline, 1 & 2 weeks after start of treatment

Onderzoeksproduct en/of interventie

14 days treatment with valproic acid (30mg/kg body weight/day) and hydralazine (150mg / day)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 18 years
- Inoperable or metastasized neuroendocrine tumor with well-differentiated histology (grade 1 or 2)
- SSTR2 negativity on 68Ga DOTATATE PET scan, defined as tumor uptake on 68Ga-DOTATATE PET CT below that of the liver

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Hypotension, defined as systolic blood pressure < 90 mmHg
- Heart failure, defined as NYHA III-IV
- Impaired kidney function, defined as creatinine clearance < 50 ml/min
- Impaired liver function, defined as bilirubin or liver transaminases > 3 times upper normal range
- Uncontrolled hormonal symptoms including severe diarrhea, defined as > 5 loose stools / day
- Severe hypoalbuminemia, defined as serum albumin concentration < 25 g/L
- Epilepsy
- Known allergies / intolerances to valproic acid or hydralazine
- Existing drug treatment which cannot be stopped and interacts or interferes with study drugs
- Inability to provide informed consent

- End of life care

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	10
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:	13-05-2019
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	NL7726
Ander register	METC Erasmus MC : MEC-2019-0031

Resultaten