Effectiveness of Somatostatin Analogues in patients with Gastric Antral Vascular Ectasia and symptomatic gastrointestinal bleeding: SAGAVE Pilot study

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The Somatostatin analogue Octreotide will is safe and effective in decreasing the need for red blood cell transfusions or intravenous iron infusions in patients with refractory anemia due to Gastric Antral Vascular Ectasia (GAVE) despite endoscopic...

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

Samenvatting

ID

NL-OMON21472

Bron
NTR

Verkorte titel
SAGAVE

Aandoening

Gastric Antral Vascular Ectasia (GAVE)

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Radboudumc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is a ‘successful response’, defined as a decrease of ≥50% in the number of red blood cell transfusion units and/or intravenous iron infusion units given during the baseline period (26 weeks prior to study inclusion) and during the treatment study period (26 weeks).

Toelichting onderzoek

Achtergrond van het onderzoek

Gastric Antral Vascular Ectasia (GAVE) is an important cause of difficult to manage bleeding, especially in older patients. There is a lack of effective, long-term treatment in patients with GAVE. Many patients are therefore transfusion dependent due to rebleeding despite endoscopic intervention. In other vascular disorders of the gastrointestinal tract (angiodysplasia and hereditary hemorrhagic telangiectasia) the Somatostatin analogue Octreotide appears to decrease bleeding episodes. The aim of this multicenter, prospective cohort study is to assess the efficacy of octreotide in decreasing the need for blood transfusions and/or iron infusions in patients with refractory anemia due to GAVE despite endoscopic intervention. All patients will receive 20 mg Sandostatin LAR once every four weeks for 26 weeks. The main study parameter is a ‘successful response’, defined as a decrease of ≥50% in the number of red blood cell transfusion units and/or intravenous iron infusion units given during the baseline period (26 weeks prior to study inclusion) and during the treatment study period (26 weeks). Important secondary outcome measures are the difference in haemoglobin and ferritin levels between baseline and during the treatment study period and difference in quality of life and level of fatigue. The burden consists of extra visits (4 times), physical examinations (2 times), blood samples (4 times), and questionnaires (2 times). Patients will also be exposed to the somatostatin analogue Sandostatin LAR and thereby are at risk for the known side-effects. The potential benefit for participating patients is that Sandostatin may reduce the need for blood transfusions by decreasing the number of rebleeds in these patients.

Doel van het onderzoek

The Somatostatin analogue Octreotide will is safe and effective in decreasing the need for red blood cell transfusions or intravenous iron infusions in patients with refractory anemia due to Gastric Antral Vascular Ectasia (GAVE) despite endoscopic intervention.

Onderzoeksopzet

The duration of the study is 26 weeks (6 months). Four visits are scheduled (at baseline, 4

weeks, 12 weeks and 26 weeks). There is also a follow-up visit at 30 weeks.

Onderzoeksproduct en/of interventie

20 mg Sandostatin LAR once every four weeks for 26 weeks.

Contactpersonen

Publiek

Radboudumc
Lia Goltstein

0646366190

Wetenschappelijk

Radboudumc
Lia Goltstein

0646366190

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Patients older than 18 years with written informed consent.
2) Endoscopic diagnosis of GAVE, confirmed within the last 12 months
3) Endoscopic refractory: at least 1 endoscopic APC, RFA, or other treatment modality performed within 12 months OR unable to receive endoscopic treatment (e.g. Pacemaker, ICD) OR patient has repeatedly indicated that they do not want endoscopic treatment OR treating physician had deemed further endoscopic treatment not relevant
4) Substantial transfusion dependency: at least 4 blood units and / or intravenous iron in the 6 months prior to study inclusion with:
a. At least one serum ferritin below < 30 ug/l within the last 6 months requiring iron infusion above or equal to 1 g and/or
b. Haemoglobin below 5.6 mmol/l (9.0 g/dl) or are in need of transfusions due to anaemia related symptoms within the last 6 months requiring blood transfusion above.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Insulinoma
2) Uncontrolled diabetes mellitus as defined by HbA1c >64 mmol/ml, despite adequate therapy,
3) Symptomatic cholecystolithiasis (possible side effect octreotide),
4) Liver cirrhosis Child-Pugh C
5) Patients with other plausible causes of gastrointestinal bleeding (e.g. severe portal hypertensive gastropathy and oesophageal varices which have recently bled)
6) Chronic or acute pancreatitis
7) Bradycardia (heart rate below 50)*
8) Hypersensitivity to the active ingredient (octreotide) or to auxiliary materials of the study medication
9) Severe disease/comorbidities with a life expectancy < 1 year
10) Pregnancy or nursing women or women who have a pregnancy wish during the study period.
11) Women of childbearing potential who do not have a confirmed menstrual period and a negative, highly sensitive urine or serum pregnancy test < 7 days before inclusion

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 gestart
(Verwachte) startdatum:	10-08-2020
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	10-08-2020
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	NL8824
Ander register	CMO Regio Arnhem-Nijmegen : METC2020-6914

Resultaten