PowerSpiral Enteroscopy: Multicenter Prospective Study on Performance and Safety Including Patients With Altered Gastrointestinal Anatomy

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

Samenvatting

ID

NL-OMON20350

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Small-Bowel diseases requiring enteroscopy for diagnosis or interventions. The majority are vascular disease with bleeding.

Ondersteuning

Primaire sponsor: St Antonious hospital, Postbus 2500, 3430 EM, Nieuwegein, The Netherlands
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary aim of this study was to evaluate the efficacy in terms of diagnostic and therapeutic yield of PSE in patients undergoing enteroscopy by both antegrade and/or retrograde approaches for suspected small-bowel disease.

Toelichting onderzoek

Achtergrond van het onderzoek

PowerSpiral enteroscopy (PSE) is a recent advancement in enteroscopy. Data are scarce on the utility and safety of PSE. No data is available on the utility of this technique in patients with altered gastrointestinal (GI) anatomy.
This study aimed to evaluate the efficacy of PSE including rate of total enteroscopy in patients undergoing enteroscopy for suspected small-bowel disease including those with altered GI anatomy.
A multicenter prospective study evaluated consecutive patients with symptomatic small-bowel disease who underwent enteroscopy over a 12-month period.

Doel van het onderzoek

Powerspiral enteroscopy provides an effective endoscopic procedure. Total small-bowel enteroscopy can be achieved, in one or two sessions, even in the presence of altered gastro-intestinal anatomy. It provides a great reduction of the enteroscopy procedure time. For both antegrade and retrograde PSE procedures, propofol sedation is sufficient and safe.

Onderzoeksopzet

1. inclusion in the study and providing informed consent
2. performing the procedure (60-90) min
3. Contact after 7 days for adverse events

Onderzoeksproduct en/of interventie

Performing enteroscopy using the motorized powerspiral for diagnosis and management of small bowel disease. For example, dilatations of stenosis or performing endotherapy for bleeding lesions. In addition to aquiring tissue samples for histopathology.

Contactpersonen

Publiek

St Antonious hospital, Postbus 2500, 3430 EM, Nieuwegein, The Netherlands
Abdulbaqi Al-Toma

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Wetenschappelijk

St Antonious hospital, Postbus 2500, 3430 EM, Nieuwegein, The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age above 18 years
2. Patients with suspected small-bowel pathology indicated for diagnostic and/or therapeutic enteroscopy based on clinical presentation, small-bowel imaging, or video capsule enteroscopy
3. Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contraindications for endoscopy because of comorbidities
2. Unable to provide written informed consent
3. Patients with known severe gastro-intestinal tract inflammation, intestinal obstruction, gastroesophageal varices or eosinophilic esophagitis that preclude a safe enteroscopy procedure
4. Coagulopathy or thrombocytopenia that could not be corrected by blood product transfusion
5. Pregnant patients
6. Health status: American Society of Anesthesiologists (ASA) class >3
7. Inability to tolerate Propofol sedation or general anesthesia for any reason

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:	01-03-2020
Aantal proefpersonen:	130
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	03-05-2021
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	NL9452
Ander register	MEC-U (Medical Reseach Ethics Committee United), date 14-09-2020 : MEC-U (Registration number W20.204)

Resultaten