

Evaluation of Clinical and laboratory outcomes of Rivaroxaban in short Bowel syndrome patients depending on Long term parenteral nutrition: a prospective cohort study

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Rivaroxaban in patients with short bowel syndrome is absorbed well and improves quality of life.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28143

Bron

Nationaal Trial Register

Verkorte titel

TINCRBEL study

Aandoening

short bowel syndrome, thrombosis, catheter related thrombosis

Ondersteuning

Primaire sponsor: Amsterdam University Medical Center

Overige ondersteuning: Investigator initiated study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical outcomes after one year, related to the laboratory levels per subject:

* Efficacy: venous thromboembolism, cerebrovascular stroke

* Safety: (major) bleeding cfr. ISTH criteria, mortality

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale

Short bowel syndrome patients are patients at high risk for thrombosis and bleeding. In a recent retrospective cohort of 266 patients, 11% developed a recurrent thrombosis and 4.3% developed a bleeding complication within one year. In recent years, direct oral anticoagulants (DOACs) have emerged as a first-line option for the treatment and prevention of venous thromboembolism. A prior pilot study showed that the DOAC rivaroxaban is well absorbed in most patients, but not in all. Therefore in AMC patients with short bowel syndrome, with a lifelong indication for anticoagulation who are prescribed rivaroxaban 20 mg 1dd1, regular "absorption checks" are performed as clinical routine to assure that the adequate plasma levels are obtained. However, in this specific patient population there is no data yet on clinical outcomes showing the relation between the DOAC plasma levels and therapeutic efficacy. This study is conducted to test the following hypotheses:

- 1) Adequate plasma levels (anti Xa levels and drug concentration) of rivaroxaban in a patient population suffering from short bowel syndrome correlate with favorable clinical outcomes, in particular less recurrent thrombosis.
- 2) Rivaroxaban in patients suffering from short bowel syndrome who have a lifelong indication for anticoagulants leads towards improvement of quality of life.

Objective

- 1) To evaluate attained rivaroxaban plasma levels, assessed anti Xa levels and drug concentration, in patients with short bowel and to relate these blood levels to clinical outcomes.
- 2) To evaluate the change in quality of life in this patient population.

Study design and population

We choose to perform a prospective cohort drug study with minimally invasive measurements where patients with short bowel syndrome who are taking rivaroxaban according to clinical routine will be observed during a period of at least one year. Patients ≥ 18 years old are eligible for the study if they are diagnosed with SBS by the AMC outpatient clinic endocrinology, if they have a DOAC-registered indication for life long anticoagulants (atrial fibrillation, thromboprophylaxis and treatment of VTE) and if they have no contra-indications for DOAC's. The invasive measurements consist of 12 extra blood draws and 2 SF-36 quality of life questionnaires over a period of half a year. The intervention is not the prescribing of rivaroxaban as rivaroxaban is prescribed for the indication which it was registered for.

Main study parameters/endpoints:

- Clinical outcomes: VTE, bleeding, mortality- Laboratory outcomes: anti Xa levels and plasma concentrations of rivaroxaban
- SF-36 questionnaire

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are no specified burden or risks associated with participation, as in clinical scenario the same assessments would be done, except for 4 extra blood draws per day (and filling in two SF-36 questionnaires on quality of life. As it is a drug study, a moderate risk has been assigned to this study.

Doel van het onderzoek

Rivaroxaban in patients with short bowel syndrome is absorbed well and improves quality of life.

Onderzoeksopzet

T0 = baseline

T1 = 3 months

T2 = 6 months

Onderzoeksproduct en/of interventie

Blood samples (pharmacokinetic profile) and quality of life questionnaires

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Diagnosis of short bowel syndrome (<170 cm after Treitz ligamentum) or intestinal malabsorption, diagnosed by an endocrinologist in the AMC
- Current use of TPN
- Age 18 years or over
- Indication for anticoagulant therapy before the start of TPN (DOAC, vitamin K antagonist, heparin) such as stroke prevention in patients with atrial fibrillation, prevention of venous thromboembolic events

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

3. Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study

- Symptomatic thrombosis at inclusion
- Major bleeding defined according to the International Society on Thrombosis and Haemostasis(11) in the 6 months prior to start participation
- Contraindication for direct oral anticoagulant
 - o Chronic treatment with NSAID/Cytochrome P450/PgP dependent co-medication
 - o Severe renal (eGFR<15) or hepatic impairment (Child Pugh score B or C) o Pregnancy or inadequate use of contraception
 - Gastrectomy or
- Medical or psychological condition that would not permit completion of the study or signing of informed consent, including life expectancy less than six months, or unwillingness to sign informed consent;
- Non-compliance or inability to adhere to treatment or to the follow-up visits.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-08-2018
Aantal proefpersonen: 30
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 08-08-2018
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
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NTR-new	NL7225
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NTR-old	NTR7425
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Ander register METC Amsterdam UMC // ABR Toetsingonline : 2018_84 // NL63863.018.18

Resultaten