Verbetering van stolseloplossing met een medicijn voor acht weken

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Treatment with Venoruton prevents RVO, which is a surrogate outcome of PTS.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Embolieën en trombose
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26364

Bron
Nationaal Trial Register

Verkorte titel
The RESOLVE-DVT Study

Aandoening

- Embolieën en trombose

Aandoening

Acute, proximal DVT of the lower extremity

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Maastricht University Medical Center (MUMC+)
Overige ondersteuning: Netherlands Thrombosis Foundation

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

Presence of RVO, defined as a vein diameter ≥2mm on DUS during full compression.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: One in three patients experiences chronic signs and symptoms in the affected leg after deep vein thrombosis (DVT). This is referred to as the post-thrombotic syndrome (PTS). Current prevention of PTS is limited to elastic compression therapy (ECT) in the acute phase of DVT. Considering the major societal burden associated with PTS, supplementation of current prevention with an effective pharmacotherapeutic therapy could be of high value. Since the pathogenesis of PTS is mediated through inadequate thrombus resolution causing damage to vessel walls and increasing inflammation, the venoactive flavonoids with their vasoprotective and anti-inflammatory properties provide an excellent candidate. As investigational medicinal product, the highly effective flavonoid O-β-hydroxyethylrutoside (Venoruton) was chosen. Objective: To assess the effect of Venoruton on PTS-associated aspects of DVT resolution. Study design: A single-center, randomized, controlled, pilot trial. Study population: Adults presenting themselves at the emergency department (ED) with a first, acute, proximal DVT of the lower extremity. Intervention: Administration of 500 mg Venoruton twice daily for 8 weeks following DVT, in addition to standard treatment by ECT and anticoagulant therapy. Main study parameters: The primary study outcome is residual vein obstruction (RVO), assessed by duplex ultrasound (DUS) at 12 weeks after DVT. Main secondary outcomes are levels of circulating biomarkers and severity of PTS-characterizing clinical signs at baseline, 1 week, 4 weeks, 8 weeks and 12 weeks. Moreover, we measure quality of life (QoL) and PTS-characterizing symptoms at baseline, 4 weeks and 12 weeks. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients have a follow-up duration of 12 weeks after diagnosis of DVT. In addition to their visit at the ED, patients will visit the outpatient clinic four times during follow-up. At each visit secondary outcomes are measured through questionnaires, blood withdrawal and assessment of the affected leg. Two visits (4 and 12 weeks) coincide with the regular clinical care pathway. The primary outcome, RVO, is measured at 12 weeks after DVT by DUS. Patients allocated to the intervention group will take two oral tablets daily over a period of eight weeks. Venoruton has been established as safe with rarely occurring, mild, reversible side-effects through many years of experience. Masking: while patients are aware of their treatment allocation, the physicians and researchers are not, as to provide unbiased outcome assessment.

Doel van het onderzoek

Treatment with Venoruton prevents RVO, which is a surrogate outcome of PTS.

Onderzoeksopzet

Biomarkers and clinical signs at baseline, 1 week, 4 weeks, 8 weeks and 12 weeks; Symptoms and QoL at baseline, 4 weeks and 12 weeks; RVO at 12 weeks; Medication adherence and ECT compliance at 1 week, 4 weeks, 8 weeks and 12 weeks; Pill count Venoruton at 8 weeks; Pill count DOAC at 12 weeks.

Onderzoeksproduct en/of interventie

Treatment with Venoruton 500mg film-coated tablets oral twice daily for eight weeks after DVT

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult ; Objectively confirmed DVT of lower extremity by DUS; Proximal localisation of DVT; Acute onset of DVT (symptoms for ≤ 7 days at presentation); Willing and able to give written

consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Previous DVT; Bilateral DVT; Pre-existent chronic venous insufficiency; Active malignancy or inflammatory disease; Pregnancy; Indication for therapeutic thrombolysis; Contra-indication for DOAC

Onderzoeksopzet

Opzet

Fase onderzoek:	3
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep
Doel:	Preventie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-12-2020
Aantal proefpersonen:	44
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	09-02-2020

Soort:	Eerste indiening
Toetsingscommissie:	METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht Postbus 5800 6202 AZ Maastricht 043 387 6009 secretariaat.metc@mumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52521
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8365
CCMO	NL73142.068.20
	NCT04670432
OMON	NL-OMON52521

Resultaten