Anticoagulant Medicines for Balloon Pulmonary Angioplasty

Gepubliceerd: 26-01-2021 Laatst bijgewerkt: 15-05-2024

It is unclear if DOACs are superior or inferior compared to VKAs in CTEPH/CTED patients regarding (peri-procedural) bleeding and long-term (thrombotic) complications.

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

Samenvatting

ID

NL-OMON22258

Bron
NTR

Verkorte titel
AIM-BPA

Aandoening

Chronic Thromboembolic Pulmonary Hypertension (CTEPH), Chronic Thromboembolic Disease (CTED)

Ondersteuning

Primaire sponsor: St Antonius Hospital, Nieuwegein, the Netherlands
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A composite of periprocedural bleeding (life-threatening or disabling bleeding, vascular injury or access site complications) and lung injury within 24 hours after BPA on a per-session basis.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Historically, all patients with chronic thromboembolic pulmonary hypertension (CTEPH) and chronic thromboembolic disease (CTED) were treated with vitamin K antagonists (VKAs). Nowadays, the use of direct oral anticoagulants (DOACs) is increasing. Nevertheless, it is unclear if DOACs are superior or inferior compared to VKAs in CTEPH patients receiving balloon pulmonary angioplasty (BPA) regarding (peri-procedural) bleeding, long-term (thrombotic) complications and clinical outcome.

Objective: We evaluate the safety and efficacy of DOACs versus VKAs in CTEPH/CTED patients receiving BPA. The effect of anticoagulant type on long-term safety and efficacy and quality of life in these patients is evaluated on a per-patient basis.

Study design: Multicentre, randomized controlled, open-label pilot trial.

Study population: All consecutive patients with an established CTEPH/CTED diagnosis and accepted for BPA treatment are eligible for inclusion in this study. Patients with an indication for a specific anticoagulation treatment, a high bleeding risk or a life-expectancy less than 1 year are excluded.

Intervention: The patients will be randomized to VKA or DOAC prior to the first BPA procedure.

Main study parameters/endpoints: The primary endpoint is the combination of periprocedural bleeding (life-threatening or disabling bleeding, vascular injury or access site problems) and lung injury within 24 hours after BPA, on a per-session basis. In addition, other (long-term) safety and efficacy endpoints will be assessed per-patient.

Doel van het onderzoek

It is unclear if DOACs are superior or inferior compared to VKAs in CTEPH/CTED patients regarding (peri-procedural) bleeding and long-term (thrombotic) complications.

Onderzoeksopzet

After each BPA and at 3,6, 12 and 18 months

Onderzoeksproduct en/of interventie

VKA versus DOAC in CTEPH/CTED patients receiving BPA

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Established CTEPH or CTED diagnosis according to the guideline(12), with at least 3 months of anticoagulation treatment.
- Inoperable patients, patients reluctant to undergo surgery or patients with residual PH after PEA and accepted for BPA treatment.
- Accessible thromboembolic lesions for BPA.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Operable CTEPH or CTED patients accepted for PEA.
- Contra-indications for BPA: right-sided mechanical heart valve, thrombus or myxoma in the right atrium or right-sided valvular endocarditis.
- Contra-indications for DOAC treatment: e.g. mechanical heart valves, myocardial thrombus, triple positive antiphospholipid syndrome, morbid obesity and (status after) bariatric treatment or major gastrointestinal resections and combination with CYP3A4 inhibitors and inductors. Anticoagulation dosage should be adjusted depending on renal function and drug interaction.
- High risk patients for bleeding complications: previous life-threatening bleeding (e.g. intracranial bleeding), age >80 years or pulmonary vascular resistance > 10 woods units (WU).

- Life-expectancy <1 year.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-03-2021
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	26-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53991
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9222
CCMO	NL75523.100.20
OMON	NL-OMON53991

Resultaten

Samenvatting resultaten
N/A