Periprocedural continuation versus interruption of oral anticoagulant drugs during transcatheter aortic valve implantation

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Periprocedural continuation of oral anticoagulants is safe and might decrease thromboembolic complications without an increase in bleeding complications at 30 days.

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

Samenvatting

ID

NL-OMON26988

Bron
NTR

Verkorte titel
POPular PAUSE TAVI trial

Aandoening

Aortic Valve Stenosis

Ondersteuning

Primaire sponsor: St Antonius Hospital, Nieuwegein, the Netherlands
Overige ondersteuning: Onderzoeksfonds St. Antonius Ziekenhuis; ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A composite of cardiovascular mortality, stroke, myocardial infarction, major vascular complications and major, disabling and life-threatening bleeding complications at 30 days post TAVI as defined by the Valve Academic Research Consortium(VARC)-2 criteria.

Toelichting onderzoek

Achtergrond van het onderzoek

Transcatheter aortic valve implantation (TAVI) is a rapidly growing treatment option for patients with aortic valve stenosis. Stroke is a feared complication of TAVI, with an incidence of around 4-5% in the first 30 days. Up to 50% of patients undergoing TAVI have an indication for oral anticoagulants (OAC) mostly for atrial fibrillation. OAC use during TAVI could increase bleeding complications, but interruption during TAVI may increase the risk for thromboembolic events (i.e. stroke, systemic embolism, myocardial infarction). Recent observational data suggest that periprocedural continuation of OAC is safe and might decrease the risk of stroke. Beside the potential reduction of thromboembolic events, continuation of OAC is associated with an evident clinical ancillary benefit for patients and staff. Since periprocedural OAC interruption not infrequently leads to misunderstanding and potentially dangerous situations, when patients are not properly informed before hospital admission or may experience difficulties with the interruption regimen.

Doel van het onderzoek

Periprocedural continuation of oral anticoagulants is safe and might decrease thromboembolic complications without an increase in bleeding complications at 30 days.

Onderzoeksopzet

Hospital discharge, 30 days, 3 months

Onderzoeksproduct en/of interventie

Uninterrupted periprocedrual oral anticoagulant treatment

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Planned transfemoral transcatheter aortic valve implantation procedure
- Established indication for oral anticoagulation
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients at high risk for thromboembolism for who interruption of oral anticoagulants is no option:
- Mechanical heart valve prosthesis
- Intracardiac thrombus
< 3 months after venous thromboembolism
< 6 months after transient ischemic attack or stroke in patients with atrial fibrillation

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-11-2020
Aantal proefpersonen:	858
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	27-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56111
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9066
CCMO	NL73805.100.20
OMON	NL-OMON56111

Resultaten