# 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**
Nationaal Trial Register

**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: | Actieve controle groep |

### 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