The influence of CYP2C19 loss-of-function alleles on atherothrombotic events in patients on clopidogrel after endovascular aneurysm repair (EVAR)

Gepubliceerd: 29-03-2021 Laatst bijgewerkt: 15-05-2024

We hypothesize that poor and intermediate CYP2C19 metabolizers using clopidogrel after endovascular aneurysm repair (EVAR) have an increased risk of adverse clinical events related to arterial thrombosis.

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

Samenvatting

ID

NL-OMON29281

Bron
Nationaal Trial Register

Verkorte titel
GEN-EVAR

Aandoening

Abdominal Aortic Aneurysm

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Radboudumc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome will be the occurrence of adverse clinical events related to arterial thrombosis such as incidence of Major Adverse Cardiovascular Events (MACE) and Major Adverse Limb events (MALE).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Antiplatelet therapy is recommended in all patients with an aneurysm of the abdominal aorta (AAA) and after endovascular aneurysm repair (EVAR). These patients increasingly receive clopidogrel instead of aspirin. A notable portion of the population carries one or two CYP2C19 loss-of-function allele(s) which results in a limited ability to convert the prodrug clopidogrel into its active metabolites. We hypothesize that poor and intermediate CYP2C19 metabolizers using clopidogrel after endovascular aneurysm repair (EVAR) have an increased risk of adverse clinical events related to arterial thrombosis.
Objective: To establish the relationship between the presence of CYP2C19 loss-of-function alleles and the incidence of atherothrombotic events in patients receiving clopidogrel after EVAR.
Study design and population: GEN-EVAR is a cross-sectional, retrospective cohort study including patients (n=300) using clopidogrel after EVAR.
Intervention: After written informed consent, patients will be invited to perform a buccal swab test at home. The samples will be analyzed with the Spartan Cube, which is a point-of-care device to detect CYP2C19 *2 and *3 loss-of-function alleles. Clinical data on the occurrence of atherothrombotic events will be retrieved from the electronic patient records.
Main study parameters/endpoints: The primary outcome will be the occurrence of adverse clinical events related to arterial thrombosis such as incidence of Major Adverse Cardiovascular Events (MACE) and Major Adverse Limb events (MALE). The incidence of in-stent thrombosis, mural thrombosis and bleedings are secondary endpoints.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be invited to perform a buccal swab test at home, the burden for the patients is therefore low and there are no risks involved.

Doel van het onderzoek

We hypothesize that poor and intermediate CYP2C19 metabolizers using clopidogrel after endovascular aneurysm repair (EVAR) have an increased risk of adverse clinical events related to arterial thrombosis.

Onderzoeksopzet

12 months

Onderzoeksproduct en/of interventie

Testing for carriage of the CYP2C19*2 and *3 loss-of-function alleles.

Contactpersonen

Publiek

Radboudumc
Josephine Kranendonk

06-25533107

Wetenschappelijk

Radboudumc
Josephine Kranendonk

06-25533107

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult patients (age 18 years)
- Obtained written informed consent
- Patients with the ability to perform a buccal swab at home
- Patients who underwent EVAR for an infrarenal AAA between January 2016 and April 2020, including those that were additionally treated with an iliac branched device and/or coiling of the internal iliac artery
- Patients who are on continues treatment with clopidogrel as single antiplatelet therapy since EVAR

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with a known CYP2C19 genotype or metabolizer state
- Patients who are treated with other anticoagulants such as aspirin, ticagrelor, prasugrel, coumarins or Non vitamin K Oral Anti-Coagulants (NOACs)
- Patient treated for a juxtarenal AAA with Fenestrated EVAR, Chimney EVAR or open surgical repair
- Patients that have used clopidogrel only temporary after EVAR

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	29-03-2021
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data will be accessible through the DANS EASY repository, using Dublin Cor metadata scheme

Ethische beoordeling

Positief advies

Datum:	29-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55153
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9376
CCMO	NL74501.091.20
OMON	NL-OMON55153

Resultaten

Samenvatting resultaten
Not applicable