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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29281

Source
Nationaal Trial Register

Brief title
GEN-EVAR

Health condition

Abdominal Aortic Aneurysm

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Radboudumc

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

The incidence of in-stent thrombosis, mural thrombosis and bleeding complications

Study description

Background summary

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.

Study objective

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.

Study design

12 months

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	29-03-2021
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

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

Ethics review

Positive opinion

Date:	29-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55153
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
Not applicable