Platelet reactivity in patients with Atrial Fibrillation and Coronary Artery Disease under IIa antagonists and Xa antagonists

Published: 30-10-2019
Last updated: 10-04-2024

Study endpoints: This study will capture the following endpoints: 1. To determine if use of IIa antagonist(Dabigatran) is associated with increased platelet activation as compared to Xa(Apixaban, edoxaban, rivaroxaban) 2. To determine if use of IIa...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON52390

Source
ToetsingOnline

Brief title
PACX

Condition

- Cardiac arrhythmias

Synonym
Atriumfibrilleren, Boezemfibrilleren

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Sint Antonius onderzoeksfonds

Intervention

Keyword: Atrial Fibrillation, coronair lijden, NOAC, Platelet reactivity

Outcome measures

Primary outcome

• Percentage platelet bound P-selectin expression

Secondary outcome

• Levels of Tromboxane B2

• Platelet reactivity as measured with multiple platelet function tests

(Appendix A)

• Fibrinolysis activity as measured with Plasmin-antiplasmin complex (PAP),

D-dimers and TAFIa levels as well as in vitro clot-lysis time between the three

drugs will be contrasted.

• Fibrin formation markers (fibrinopeptide A and B and soluble fibrin) and the

in vitro clotting time

• Overall thrombus formation and clot lysis assessment using

thromboelastography (TEG) en T-TAS

Study description

Background summary

This is a single blinded (investigators blinded) crossover trial of 40 patients, diagnosed with AF on a steady state level of an anticoagulant. Patients will switch once medication after 2 weeks(IIa antagonist en Xa antagonist). Platelet function tests and fibrinolysis tests will be performed in blood samples collected at baseline(Before use of the medication) and after 2 weeks.

Study objective

Study endpoints: This study will capture the following endpoints:
1. To determine if use of IIa antagonist(Dabigatran) is associated with increased platelet activation as compared to Xa(Apixaban, edoxaban, rivaroxaban)
2. To determine if use of IIa antagonist(Dabigatran) is associated with decreased fibrinolysis activation as compared to Xa(Apixaban, edoxaban, rivaroxaban)

Study design

Prospective cross-over study.

Intervention

Use of Accenocoumarol, Apixaban and Dabigatran

Study burden and risks

All patients switch medication after 2 weeks and switch back. Besides regular risks of use of registered medication(e.g. small bleedings and brushes) no extra risks involved

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient must meet all of the following criteria:
• Male or female >= 18 years
• AF with stable coronary disease (either angiographically proven, undergone an intervention or history of MI)
• Use of OAC(NOAC)
• Patients with signed informed consent

Exclusion criteria

• Patients who are unable to give informed consent
• Patients with hematologic, renal (estimated glomerular filtration rate <45 ml/min/1.73m2), hepatic (liver enzymes >2 times the upper limit of normal), inflammatory (CRP >2 times the upper limit of normal)or neoplastic disorders
• Patients using any other antithrombotic drugs (e.g., aspirin, GPIIbIIIa etc.)
• Patients using nonsteroidal anti-inflammatory drugs, corticosteroids, or hormone replacement therapy
• Patients with valvular AF(either articfial heart valves, medium to severe mitral valve stenosis or <3 months after bioprosthetic heart valves) and AF precipitated by hyperthyroidism or any acute infection
• Patients with coronary disease resulting from demand ischaemia

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-07-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-02-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL69712.100.19