Tailoring P2Y12 Inhibiting Therapy in Patients requiring Oral Anticoagulation after undergoing Percutaneous Coronary Intervention: The Switching Anti-Platelet and Anti-Coagulant Therapy - 2 Study

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The aim of this study is to assess the pharmacodynamic effects of different P2Y12 inhibiting therapy (clopdiogrel vs ticagrelor) in patients at high risk for HPR identified according to the ABCD-GENE score in PCI treated patients also requiring OAC...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON52027

Source
ToetsingOnline

Brief title
SWAP-AC-2 study

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
coronary artery disease, percutaneous coronary intervention

Research involving
Human

Sponsors and support

Primary sponsor: University of Florida College of Medicine
Source(s) of monetary or material Support: St. Antonius Heart Center Research and Innovation

Intervention

Keyword: Antithrombotic therapy, Percutaneous coronary intervention

Outcome measures

Primary outcome

Level of platelet reactivity measured by VerifyNow (PRU units)

Secondary outcome

Additional exploratory end points will include the comparisons between

clopidogrel-treated patients with ABCD-Gene score<10 and the other 2 arms, as

well as comparisons between groups of rates of HPR.

Study description

Background summary

The combination of aspirin plus a P2Y12 receptor inhibitor, also known as dual antiplatelet therapy (DAPT), is the cornerstone of treatment for patients with coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI). However, a considerable number of patients undergoing PCI also have an indication to be on treatment with an oral anticoagulant (OAC). It is estimated that 10-15% of PCI patients also have an indication to be on OAC, raising concerns on their optimal antithrombotic treatment regimen. Studies have consistently shown dropping aspirin and maintaining a P2Y12 inhibitor and OAC to be associated with reduces bleeding without any significant increase in ischemic events. Accordingly, current practice recommendations is to limit the use of aspirin to the peri-PCI period and maintain dual therapy with a P2Y12 inhibitor and an OAC. Clopidogrel is the P2Y12 inhibitor of choice in PCI patients requiring OAC. However, concerns have been raised based on the notion that a considerable number of patients may have inadequate response to clopidogrel, also known as high platelet reactivity (HPR) status, and thus be at risk for thrombotic complications. Although practice recommendations

indicate that the use of potent P2Y12 inhibitors (i.e., ticagrelor) may be considered in patients at increased thrombotic risk, they do not recommend routine testing to identify patients with HPR status. Nevertheless, consensus recommendations do indicate that the selective use of tests to define HPR status is a reasonable option in selected cases such as PCI patients requiring OAC.

Study objective

The aim of this study is to assess the pharmacodynamic effects of different P2Y12 inhibiting therapy (clopdiogrel vs ticagrelor) in patients at high risk for HPR identified according to the ABCD-GENE score in PCI treated patients also requiring OAC.

Study design

Open label RCT

Intervention

In patients with ABCD-GENE score <10: clopidogrel 75mg 1dd1
In patientes with ABCD-GENE score >=10:
Randomisation to ticagrelor 60mg 2dd1 or clopidogrel 75mg 1dd1

Study burden and risks

Both treatment strategies are in line with current guidelines and practise, thus have to extra risk for the patient.
We will perform venepuncture 3 times, which has a very small risk of bleeding or infectious complications.
The patient will have one extra visit that will take around 2,5 hours.

Considering the scientific value of this study, we consider this burden and risk acceptable.

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

• Age >= 18 years
• Willing and able to provide written informed consent
• Undergone successful PCI and treated with DAPT (aspirin plus a P2Y12 inhibitor) per standard of care
• On treatment with a novel oral anticoagulant (apixaban, dabigatran, edoxaban, or rivaroxaban) for any indication (dosing regimen will be according to standard of care and at the discretion of the treating physician)

Exclusion criteria

• Any active bleeding or history of major bleeding
• Ischemic Stroke within 1 month
• Any history of hemorrhagic or lacunar stroke, or intracranial hemorrhage
• Known non-cardiovascular disease that is associated with poor prognosis (e.g., metastatic cancer) or that increases the risk of an adverse reaction to study interventions.
• End-stage renal disease on hemodialysis
• Known severe liver dysfunction or any known hepatic disease associated with coagulopathy
• History of hypersensitivity or known contraindication to clopidogrel or ticagrelor.

• Systemic treatment with strong inhibitors of both CYP 3A4 and p-glycoprotein (e.g., systemic azole antimycotics, such as ketoconazole, and human immunodeficiency virus [HIV]-protease inhibitors, such as ritonavir), or strong inducers of CYP 3A4, i.e. rifampicin, rifabutin, phenobarbital, phenytoin, and carbamazepine
• Subjects who are pregnant, breastfeeding, or are of childbearing potential, and sexually active and not practicing an effective method of birth control (e.g. surgically sterile, prescription oral contraceptives, contraceptive injections, intrauterine device, double barrier method, contraceptive patch, male partner sterilization)
• Concomitant participation in another study with investigational drug
• Hemoglobin <=9 mg/dL
• Platelet count <=80x106/mL

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	clopidogrel
Generic name:	clopidogrel

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	ticagrelor
Generic name:	ticagrelor
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-06-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-06-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-01-2023
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
EudraCT	EUCTR2021-001418-12-NL
ClinicalTrials.gov	NCT04483583
CCMO	NL77196.100.21