RE-DUAL PCI Real life Registry: Dual Therapy with dabigatran/clopidogrel versus Triple Therapy with dabigatran/clopidogrel/aspirin in ACS patients with indication for NOAC undergoing PCI.

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A real world registry to compare dual therapy with Dabigatran/Clopidogrel to Usual care (Triple Therapy) with Dabigatran/Clopidogrel/Aspirin in patients with an indication for NOAC undergoing PCI in the setting of ACS. Hypothesis: Dual therapy with...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON50081

Source
ToetsingOnline

Brief title
REDUAL PCI REGISTRY

Condition

- Coronary artery disorders

Synonym
Anticoagulantia, percutanous coronary intervention

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: dual therapy, NOAC, PCI, triple therapy

Outcome measures

Primary outcome

The primary endpoint is the first bleeding event (major and clinically relevant non-major), as defined by the Bleeding Academic Research Council (BARC) score *2 in the 12 months follow-up.

Secondary outcome

The secondary endpoints are efficacy endpoints of thromboembolic events (myocardial infarction, stroke, systemic embolism) and death. Other secondary endpoints are a composite endpoint of thromboembolic events or death, as well as the individual thromboembolic events and stent thrombosis.

Study description

Background summary

Due to the increasing number of patients with atrial fibrillation undergoing percutaneous coronary intervention (PCI), the optimal balance between thromboembolic complications versus bleeding complications with the use of anticoagulation and
anti-platelet therapy has been investigated. In recent studies mainly in stable angina, dual therapy with novel oral anticoagulant (NOAC) based therapy and a P2Y12-inhibitor seems to be the preferred choice of treatment compared to triple therapy (vitamin K antagonist (VKA) or NOAC with P2Y12-inhibitor and Aspirin) especially reducing the risk of bleeding. VKA seems to be omitted and

NOAC is the preferred choice, reducing bleeding risk and stroke. Especially in ACS (acute coronary syndrome), real world data is missing. Subanalysis of studies looking at ACS patient with NOAC undergoing PCI shows a trend toward lower myocardial infarction rates in triple therapy NOAC-based, but the risk difference was less using full dose NOAC in dual therapy and still underpowered. In ACS the risk for thromboembolic events and ischemia is the highest and the need for addition of aspirin to reduce this risk has to be investigated. Is really needed to add aspirin to dual therapy in patients with ACS undergoing PCI? Is the use of full dose NOAC with P2Y12 inhibitor the best option?

Study objective

A real world registry to compare dual therapy with Dabigatran/Clopidogrel to Usual care (Triple Therapy) with Dabigatran/Clopidogrel/Aspirin in patients with an indication for NOAC undergoing PCI in the setting of ACS.
Hypothesis: Dual therapy with Dabigatran/Clopidogrel (RE-DUAL PCI trial based) will be superior in reducing the risk of bleeding compared to Triple therapy with Dabigatran/Clopidogrel/Aspirin in patients with an indication for NOAC undergoing PCI in the setting of ACS. Thromboembolic events, stent thrombosis and death will be evaluated for estimation of events between both groups.

Study design

Open-label, multicenter, Regisry based Randomised controlled trial (RBRCT).

Study burden and risks

With regard to burden: I think the study is a little burden for patients with regards to 2 short questionnaires. Rest is usual care. Possibly additionnal information by telephone consultation.

With regard to risks: Dual therapy is already widely used in PCI patients, also in ACS patients after consideration of bleeding versus thromboembolic risk. This is a randomized setting to see whether the previous results in studies and individual cases in daily practice actually show the same results. If patients have the same outcome in both groups with regard to thromboembolic risk, they can reduce bleeding risks with dual therapy and thus quality of life and medical intervention.
I think that patients are not at any great risk compared to standard treatment since in daily practice both therapies are applied based on insight of (interventional) cardiologist and are individualized, which makes the standard treatment choice for the whole group in general more difficult.

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
* Patients having an indication for a NOAC or will start with oral anticoagulation (NOAC). Permanent, persistent or paroxysmal atrial fibrillation are eligible.
* PCI and successful stenting with DES for ACS (unstable angina pectoris, NSTEMI, STEMI)
* Written informed consent.

Exclusion criteria

* Patients unable or unwilling to comply with the protocol or with life

expectancy shorter
than the duration of the study
* Glomerular filtration rate < 30 ml/min
* Heart valve prosthesis (mechanical or biological)
* Cardiogenic shock
* Contra-indication for NOAC, Aspirin or Clopidogrel
* Allergy to for NOAC, Aspirin or Clopidogrel
* Pregnancy
* Previous intracerebral haemorrhage
* Significant thrombocytopenia (platelet count < 50x10 9/L)
* Major bleeding according to BARC *3 within the past 12 months.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1000
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Aspirine/Ascal
Generic name:	Acetylsalicylzuur/carbasalaatcalcium
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Plavix
Generic name:	Clopidogrel
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Pradaxa
Generic name:	Dabigatran
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-08-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2020-001647-91-NL
CCMO	NL73747.096.20