What is the optimal antithrombotic strategy in patients with atrial fibrillation having acute coronary syndrome or undergoing percutaneous coronary intervention?

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

Summary

ID

NL-OMON51815

Source
ToetsingOnline

Brief title
WOEST 3

Condition

- Coronary artery disorders

Synonym
atrial fibrillation, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Daiichi Pharmaceutical,St. Antonius Onderzoeksfonds;Daiichi Sankyo

Intervention

Keyword: antithrombotic therapy, atrial fibrillation, coronary artery disease

Outcome measures

Primary outcome

Primary safety endpoint: International Society for Thrombosis and Haemostatis

(ISTH) major + clinically relevant non-major bleeding (CRNMB) at 30 days

Primary efficacy endpoint: composite endpoint of all-cause death, MI, stroke,

systemic embolism, stent thrombosis) at 30 days

Secondary outcome

Secondary endpoints: separate components of primary endpoints, net clinical

benefit, quality of life.

Study description

Background summary

A central issue in patients with atrial fibrillation (AF) and coronary artery disease (CAD) is to find the optimal balance between ischemic and bleeding risk. Combination therapy with OAC and DAPT (triple therapy) is associated with high risk of major bleeding. Omitting aspirin (dual therapy) reduces bleeding, but meta-analysis found increased risk of myocardial infarction and stent thrombosis in the first month after PCI with this strategy. In this study we propose a strategy of DAPT with temporary withdrawal of OAC during the first 30 days following PCI or ACS versus standard therapy (edoxaban and P2Y12 inhibitor).

Study objective

This study has been transitioned to CTIS with ID 2022-502140-13-00 check the CTIS register for the current data.

1. To compare bleeding risk (i.e. safety) with DAPT compared to standard therapy during the first 30 days following PCI/ACS in patients with AF
2. To compare ischemic risk (i.e. efficacy) with DAPT compared to standard therapy during the first 30 days following PCI/ACS in patients with AF

Study design

Multicentre open-label randomized controlled trial.
The safety endpoint will be analysed for superiority; the efficacy endpoint will be analysed for non-inferiority.

Intervention

Random (1:1) allocation to one month of DAPT following PCI/ACS versus standard therapy (edoxaban + P2Y12 inhibitor, and aspirin usually limited to admission). After one month all patients will be treated with edoxaban and P2Y12 inhibitor until 6 months after randomization.

Study burden and risks

See section E9

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

1. >=18 years of age
2. Undergoing PCI or presenting with ACS with elevated cardiac markers (CK/CK-MB, troponin)
3. History of or newly diagnosed atrial fibrillation or flutter with a long-term (>= 1 year) indication for OAC

Exclusion criteria

1. Contra indication to edoxaban
2. < 3 months after any stroke
3. < 3 months after venous thrombo embolism
4. Mechanical heart valve prosthesis
5. Moderate to severe mitral valve stenosis
6. Intracardiac thrombus

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):	11-01-2023
Enrollment:	1500
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	28-06-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	28-07-2022
Application type:	First submission
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
EU-CTR	CTIS2022-502140-13-00
EudraCT	EUCTR2022-001298-30-NL
ClinicalTrials.gov	NCT04436978
CCMO	NL81102.100.22