What is the optimal antithrombotic strategy in patients presenting with acute coronary syndrome having atrial fibrillation with indication for anticoagulants?

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1. To investigate the efficacy of dual therapy (omitting acetylsalicylic acid) compared to triple therapy in patients with atrial fibrillation and acute coronary syndrome.2. To investigate the safety of dual therapy (omitting acetylsalicylic acid)…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON49131

Source
ToetsingOnline

Brief title
WOEST 3 trial

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Coronary artery disorders
- Embolism and thrombosis

Synonym
heart attack, myocardial infarction

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,St. Antonius Onderzoeksfonds

Intervention

Keyword: Acute coronary syndrome, Anticoagulant, Antithrombotic therapy, Atrial fibrillation

Outcome measures

Primary outcome

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

systemic embolism, stent thrombosis.

Primary safety endpoint: ISTH major + clinically relevant non-major bleeding.

Secondary outcome

Secondary endpoints: separate components of primary endpoints, net clinical

benefit, quality of life.

Study description

Background summary

Patients with atrial fibrillation presenting with acute coronary syndrome have an indication for both oral anticoagulation (OAC) and dual antiplatelet therapy (DAPT). This triple therapy (OAC + DAPT) is associated with increased bleeding risk. Several RCTs have proven dual therapy (OAC + P2Y12 inhibitor) to reduce this bleeding risk compared to triple therapy without significant difference in efficacy (i.e. [CV-]death, stroke, recurrent MI, stent thrombosis, systemic embolism). However, none of this studies did focus on ACS patients, which are at higher thrombotic risk than patients with stable coronary artery disease. Also, none of these studies were statistically powered for efficacy, withholding the practice guidelines to change their recommendations.

Study objective

1. To investigate the efficacy of dual therapy (omitting acetylsalicylic acid) compared to triple therapy in patients with atrial fibrillation and acute coronary syndrome.
2. To investigate the safety of dual therapy (omitting acetylsalicylic acid) compared to triple therapy in patients with atrial fibrillation and acute coronary syndrome.

Study design

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

Intervention

Random (1:1) allocation to dual therapy (OAC + 1 year P2Y12 inhibitor) versus triple therapy (OAC + 1 year P2Y12 inhibitor + 1-12 moths ASA).

Study burden and risks

Currently there is no clear evidence for what antithrombotic therapy patients with ACS and A-fib should receive. In daily practise prescribing dual or triple therapy differs from hospital to hospital and from clinician to clinician. Patients with a high risk of bleeding randomised to triple therapy or patients with high thrombotic therapy randomised to dual therapy might have higher risk of complications. However, it is not clear how we should identify this group so they are not excluded from this study population. Since clinicians may be worried about safety or efficacy in patients with a seemingly unfavourable risk profile for the treatment assigned, as stated in section 8.6 the clinician may add or stop antithrombotic agents without consequences for the study follow-up.

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

Over 18 years of age
Acute coronary syndrome with elevated cardiac enzymes
Atrial fibrillation with long-term indication for oral anticoagulation

Exclusion criteria

Severe bleeding in past 3 months
Known coagulopathy
Contra-indications for intended medication (NOAC, P2Y12-remmer, ASA)
eGFR < 15 min/kg/1.73m2

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	2500
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ascal cardio 100mg
Generic name:	Carbasalate calcium 100mg
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Aspirin 80mg
Generic name:	Acetylsalicylic acid 80mg
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	17-02-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	10-03-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Not approved

Date:	24-03-2022
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
EudraCT	EUCTR2019-004805-28-NL
CCMO	NL71116.100.20