The safety of ticagrelor monotherapy after primary percutaneous coronary intervention for ST-elevation myocardial infarction and the effect on intramyocardial haemorrhage

Published: 10-01-2023
Last updated: 05-10-2024

This study has been transitioned to CTIS with ID 2024-517783-37-00 check the CTIS register for the current data. The main objective is to assess the safety and feasibility of the direct omission of aspirin after PPCI with the continuation of...

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

Summary

ID

NL-OMON56396

Source
ToetsingOnline

Brief title
STOP IMH

Condition

- Coronary artery disorders

Synonym
ST-elevation myocardial infarction; heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NWO;beurs voor de iMODERN trial;deze huidige studie vorm een verlengde van de iMODERN,Biotronic en Philips;geld initieel aangevraagd voor de iMODERN trial;deze huidige studie vorm een verlengde van de iMODERN

Intervention

Keyword: haemorrhage, monotherapy, STEMI, Ticagrelor

Outcome measures

Primary outcome

Primary endpoints:

Composite of major adverse cardiac and cerebral events (MACCE), consisting of:

- Myocardial infarction

- Stent thrombosis

- Ischemic stroke

- Cardiovascular mortality/All-cause mortality

Secondary outcome

Secondary endpoints:

• IMH and infarct size measured by CMR

• Bleeding complications BARC >= 2

• Platelet reactivity in ticagrelor monotherapy and tcagrelor + ASA

• All-cause mortality

Study description

Background summary

De-escalation of dual antiplatelet therapy (DAPT) to P2Y12inhibitor monotherapy after 1-3 months of DAPT has shown to reduce bleeding complications without an increase in thromboembolic complications when compared to standard DAPT in patients undergoing percutaneous coronary intervention (PCI). These results have been confirmed in patients with ST elevation myocardial infarction (STEMI). As most bleeding events occur in the first month after PCI, direct omission of aspirin after PCI could further reduce bleeding complications. Next to a reduction in clinical bleeding outcomes, ticagrelor monotherapy compared to DAPT may reduce the incidence and expansion of intramyocardial haemorrhage (IMH), a frequent complication after revascularisation in STEMI patients which leads to an increased infarct size and a worse prognosis. We designed this pilot trial to assess the safety regarding thromboembolic events of ticagrelor monotherapy directly after primary PCI (PPCI) in patients with STEMI and investigate whether ticagrelor monotherapy versus DAPT leads to a reduction of IMH. For this secondary endpoint we will only include an anterior STEMI subgroup, as anterior STEMI is associated with a higher incidence of IMH. We hypothesize that ticagrelor monotherapy compared to DAPT after PPCI for STEMI is safe regarding thromboembolic complications and reduces IMH and infarct size.

Study objective

This study has been transitioned to CTIS with ID 2024-517783-37-00 check the CTIS register for the current data.

The main objective is to assess the safety and feasibility of the direct omission of aspirin after PPCI with the continuation of ticagrelor monotherapy in STEMI patients.
The secondary objectives are to demonstrate the reduction of IMH and infarct size in patients receiving ticagrelor monotherapy compared to DAPT, and to compare bleeding outcomes of ticagrelor monotherapy versus DAPT directly after PPCI for STEMI.

Study design

This is an open-label, prospective multicentre randomized clinical trial (RCT) in STEMI patients undergoing PCI.

Intervention

Patients in the treatment arm will continue with ticagrelor monotherapy after PPCI. The control arm will receive ticagrelor based DAPT for 12 months.

Study burden and risks

The safety of ticagrelor monotherapy after 1-3 months of dual antiplatelet

therapy has been demonstrated in multiple large RCT*s of which two sub studies of the STEMI population confirm these results in STEMI patients. Furthermore, two pilot studies of which one included patients with NSTEMI and one patients with stable coronary artery disease, suggest that it is safe to discontinue aspirin directly after PPCI and continue treatment with a potent P2Y12 inhibitor such as prasugrel or ticagrelor.
However, the safety of ticagrelor monotherapy directly after PPCI has not yet been investigated. Therefore, we designed this pilot study with a relative small number of participants to assess the safety which will be monitored by a DSMB. We reduced the ischemic risk by excluding patients with suboptimal stent result and patients that undergo PCI for stent thrombosis. Furthermore, venagraft stenting is excluded as this is also associated with increased risk of stent thrombosis.
We think that patients/participants will benefit from this new treatment as we hypothesize that this treatment is safe and will reduce clinical bleeding complications and intra myocardial hemorrhage, improving prognosis after PCI.

Contacts

Public
Academisch Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Academisch Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients aged 18 years or older are eligible for inclusion if all of the following criteria are met:
- Clinical and electrocardiographical diagnosis of ST-elevation myocardial infarction (STEMI)
- Successful percutaneous coronary intervention (PCI) of the infarct-related vessel with a modern
drug eluting stent (DES)

Exclusion criteria

- Known allergy or contraindication for aspirin, ticagrelor or prasugrel.
- Previous PCI or MI less than 12 months ago
- Previous cardiac surgery
- Participation in another clinical study with an investigational product
- Pregnancy and breast feeding
- Concurrent use of oral anticoagulants (OAC)
- The periprocedural use of GPIIb/IIIa inhibitors
- Planned surgical intervention within 12 months of PCI
- Creatinine clearance <30 mL/min or dialysis
- PCI of stent thrombosis
- Suboptimal stent result as judged by the interventional cardiologist.
- Contra-indications for MRI or unable to undergo MRI (only applicable for the CMR subgroup population).

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-07-2023
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	acetylsalicylic acid
Generic name:	aspirin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-06-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-02-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	CTIS2024-517783-37-00
EudraCT	EUCTR2022-003218-36-NL
CCMO	NL82646.091.22