Reducing Micro Vascular dysfunction In revascularized STEMI patients by off-target properties of ticagrelor

Published: 23-03-2015
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To determine if ticagrelor at treatment steady state will be associated to an improved microvascular function as compared to prasugrel in revascularized STEMI patients.

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

Summary

ID

NL-OMON44678

Source
ToetsingOnline

Brief title
REDUCE-MVI

Condition

- Coronary artery disorders

Synonym
Heart attack, Myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Astra Zeneca

Intervention

Keyword: microvascular function, myocardial infarction, Prasugrel, Ticagrelor

Outcome measures

Primary outcome

microvascular function as determided by IMR in the infarct-related vessel at 30 days follow-up

Secondary outcome

1) microvascular function as determided the delta IMR in the infarct-related vessel (baseline vs. 1-month f-up).

2) microvascular function as determided the (delta) IMR in the non-infarct-related vessel

3) microvascular function as determided by the (delta) RHI as determined by EndoPat

4) microvascular function as determided by the (delta) level of biochemical markers

Study description

Background summary

Coronary microvascular dysfunction is highly prevalent in revacularized STEMI and has important prognostic implications.The current data suggest that ticagrelor might be superior to prasugrel in the reduction of coronary microvasculature dysfunction after revacularized STEMI. To date, no head-to-head comparison data is available of ticagrelor and prasugrel in terms of clinical outcome. Both oral P2Y12 receptor antagonist achieve a more rapid, consistent and greater platelet inhibition than clopidogrel and received a class 1 recommendation in the current guidelines.

Study objective

To determine if ticagrelor at treatment steady state will be associated to an improved microvascular function as compared to prasugrel in revascularized STEMI patients.

Study design

multicentre trial with a prospective, randomized, open-label, blinded-endpoint (PROBE) study design.

Intervention

The study population will be randomized to a maintenance dose of ticagrelor or prasugrel.

Study burden and risks

One extra visit to the outpatient clinic at 1-year follow-up with a venous puncture (for blood collection), EndoPat meusurement and two questionannaires (total time: 60 minutes)

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. Provision of informed consent
2. Patients presenting with STEMI <12 hours
3. Successful PCI of the infarct-related vessel with a modern DES
4. Intermediate stenosis in non-infarct-related vessel (50-90%)

Exclusion criteria

1. history of myocardial infarction
2. Participation in another clinical study with an investigational product during the preceding 30 days
3. history of cerebrovascular accident (CVA) or 'transient ischaemic attack' (TIA)
4. History of intracranial haemorrhage
5. indication or use of oral anticoagulant therapy (i.e. acenocoumarol)
6. severe liver dysfunction (Child-Pughscore 10-15)
7. congestive heart failure
8. cardiogenic shock
9. left ventricular ejection fraction < 35%
10. bleeding diathesis
11. age >= 75 or < 18
12. body weight < 60 kg
13. gout
14. coagulation disorders
15. severe pulmonary disease
16. pregnancy and breast feeding
17. limited life expectancy
18. platelet count < 100 000/mm3
19. history of drug addiction or alcohol abuse in the past 2 years
20. need for chronic nonsteroidal anti-inflammatory drug
21. creatinine clearance <30 mL/min or dialysis
22. chronic total occlusion (CTO)
23. Left main disease
24. allergy or contra-indication for ticagrelor or prasugrel
25. Contra-indication for adenosine
26. Patients unable to be followed on-site
27. Unable to undergo or contra-indications for MRI

28. Contra-indication for DES
29. Inability to obtain informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2015
Enrollment:	110
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Brilique
Generic name:	Ticagrelor
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Efient
Generic name:	Prasugrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	14-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2014-005363-33-NL
CCMO	NL51985.029.15