Prevention of Cerebral ischaemia in Stent Treatment for Carotid Artery Stenosis - A randomised Multi-centre phase II trial comparing Ticagrelor versus Clopidogrel with outcome assessment on MRI (PRECISE-MRI)

Published: 05-04-2017
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To investigate if antiplatelet therapy consisting of ticagrelor plus ASA is superior to clopidogrel plus ASA in preventing ischaemic brain lesions occurring as a result of CAS assessed on magnetic resonance imaging (MRI).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON47608

Source
ToetsingOnline

Brief title
PRECISE-MRI

Condition

- Central nervous system vascular disorders

Synonym
carotid narrowing; atherosclerotic carotid artey stenosis

Research involving

Human

Sponsors and support

Primary sponsor: Universitätsspital Basel (USB), Departement of Neurology and Stroke Center
Source(s) of monetary or material Support: AstraZeneca,AstraZeneca + additional funding provided by MIAC Basel,MIAC Basel

Intervention

Keyword: carotid artery, carotid artery stenting, carotid stenosis

Outcome measures

Primary outcome

The primary efficacy outcome is the presence of at least one new ischaemic

brain lesion on the second MRI scan done 1-3 days after CAS or on the third MRI

scan done 28-32 days after CAS, which had not been present on the first MRI

scan done 1-3 days before CAS.

Secondary outcome

Secondary efficacy outcomes are: (1) the total number of new ischaemic brain

lesions on MRI after CAS; and (2) the total volume of new ischaemic brain

lesions on MRI after CAS, defined as the sum of all volumes of separate DWI

lesions.

Study description

Background summary

Carotid artery stenting (CAS) is an emerging treatment for atherosclerotic carotid stenosis. The main adverse event is embolic stroke during the procedure. Current medical management to prevent peri-procedural embolisation consists of dual antiplatelet therapy with clopidogrel and ASA. Ticagrelor, a novel reversible inhibitor of the platelet adenosine diphosphate receptor

P2Y12, was superior to clopidogrel, as add-on therapy to ASA, in preventing stent thrombosis, cardiovascular outcome events, and death in patients undergoing coronary artery stenting, without causing an increase in major bleeding events. The hypothesis of the present study is that ticagrelor is superior to clopidogrel as add-on to ASA in preventing cerebral embolism during the CAS procedure.

Study objective

To investigate if antiplatelet therapy consisting of ticagrelor plus ASA is superior to clopidogrel plus ASA in preventing ischaemic brain lesions occurring as a result of CAS assessed on magnetic resonance imaging (MRI).

Study design

Randomised, active-control, open, parallel-group, international, multicentre phase II trial with blinded outcome assessment on MRI.

Intervention

Intervention: Ticagrelor 90 mg tablets will be used. Participants will receive a loading dose of 180 mg followed by a maintenance dose of 90 mg twice daily.

Control intervention: Clopidogrel 75 mg tablets will be used. Participants will receive a loading dose of 300 mg followed by a maintenance dose of 75 mg once daily.

Study burden and risks

This trial compares two current medications. De change of unknown side effects is very low. Given the expected superior effect of ticagrelor and the low risk of side effects, we believe that the benefits of treatment with ticagrelor outweighted the potential risks.

Patients will have a MRI scan 1-3 days before carotid artery stenting (CAS), 1-3 days after CAS and 28-32 days after CAS.

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

Patients with symptomatic or asymptomatic atherosclerotic carotid stenosis (*50% narrowing of the lumen) in whom revascularisation of the stenosis by CAS is planned routinely are eligible to participate in the study.

Exclusion criteria

Contraindication against use of ASA (acetylsalicylic acid), clopidogrel, or ticagrelor; anticoagulation; thrombolysis within the previous 24 hours; unable to walk unassisted (modified Rankin Scale >3); clinically unstable; acute coronary syndrome; need for any cardio-vascular surgery or intervention, or need for any other invasive procedure requiring halting of Study Medication during the Study, other than the index CAS procedure for which the patient was randomised; bradycardia; dyspnoea; contraindications against MRI (claustrophobia, metal implants, cardiac pacemaker); or participation in another intervention trial. No so-ccalled vulnerable patients will be included.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2017
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BRILINTA, BRILIQUE
Generic name:	Ticagrelor
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	CLOPIDOGREL ZENTIVA
Generic name:	Clopidogrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	05-04-2017
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	02-05-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	24-10-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-10-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-06-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-07-2019
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2015-005555-27-NL
ClinicalTrials.gov	NCT02677545
CCMO	NL58931.041.17

Study results

Date completed: 01-04-2022

Actual enrolment: 4

Summary results

Trial is onging in other countries