A randomized, double-blind, parallel group, multicentre phase IIIb study to compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischemic stroke in patients with established Peripheral Artery Disease (EUCLID Examining Use of tiCagreLor In paD)

Published: 15-11-2012
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To compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischaemic stroke in patients with established peripheral artery disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41255

Source
ToetsingOnline

Brief title
EUCLID

Condition

- Other condition
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
myocardial attack, PAD (Peripheral artery disease)

Health condition

cardiovasculair overlijden, hartaanval en beroerte

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca
Source(s) of monetary or material Support: AstraZeneca BV

Intervention

Keyword: - ABI (Ankle Brachial Index), - Adenosine Diphosphate P2Y12 receptor antagonist, - Cardiovasvulair, - PAD patients

Outcome measures

Primary outcome

Time from randomisation to first occurrence of any event in the composite of CV

death, MI, and ischaemic stroke.

Secondary outcome

1. Composite of CV death and MI, Ischaemic Stroke and Acute Limb Ischemia (ALI)

requiring hospitalization.

2. CV death.

3. MI.

4. all cause mortality.

5. Composite of CV death and MI, all-cause Stroke (ischaemic or haemorrhagic)

6. Acute Limb Ischemia (ALI) requiring hospitalization

7. All lower Revascularization

8. All revascularization procedures.

Study description

Background summary

Atherosclerosis with associated arterial thrombosis is a systemic disease that can affect the cardiovascular, cerebrovascular and the peripheral vascular systems. Atherosclerosis of the arteries supplying the limbs is referred to as Peripheral artery disease (PAD).
Patients with PAD have a significant systemic atherosclerotic disease burden. Clinical manifestations associated with lower extremity PAD include decrements in functional capacity and quality of life, including loss of limb. Patients with PAD also have elevated levels of platelet activity and are at substantial increased risk for platelet mediated adverse events, such as myocardial infarction (MI), ischaemic stroke, and cardiovascular (CV) death.

In the CAPRIE study, clopidogrel, an irreversible adenosine diphosphate (ADP) receptor antagonist, has shown particular benefit in a PAD population, when compared with ASA alone.

Ticagrelor (AZD6140) is a reversibly-binding, potent, oral adenosine diphosphate P2Y12 receptor blocker. In the PLATO study, ticagrelor was shown to be superior to clopidogrel in an ACS population, when given in addition to aspirin (ASA). Since established lower extremity PAD is closely associated with atherosclerosis with vulnerable plaques and intravascular macro-and microthrombosis in other vascular territories, it is likely that more complete platelet inhibition may prevent additional atherothrombotic events in this population.

The current study is being conducted to determine whether treatment with ticagrelor, given as antiplatelet monotherapy, will reduce the incidence of atherothrombotic ischaemic events compared to treatment with clopidogrel monotherapy as measured by the composite of CV death MI, and ischaemic stroke in a population with established PAD.

Study objective

To compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischaemic stroke in patients with established

peripheral artery disease.

Study design

Randomised, double blind, parallel group, multicentre phase IIIb study.

Intervention

Patients will receive ticagrelor 90 mg orally bd/ placebo or clopidogrel 75 mg orally ob/ placebo for a minimum treatment period of 18 months.

Study burden and risks

The patient is asked to visit the site at least 8 times and maximum 11 times. The total time will last 8-11 hour.

Blood samples will be taken in this study. The total volume of blood that will be collected is approximately 23 ml.

The patient will be asked to fill out a short questionnaire on his/ her quality of life and condition at maximum 5 visits.

The patient will undergo one physical examination and will have one electrocardiogram.

Woman of child-bearing potential have to provide a urine sample to test for pregnancy.

The patient will be asked to undergo an ABI measurement for a maximum of 9 times.

The study medication may cause some side effects. The taking of blood sample may cause some discomfort and there is the possibility of bruising.

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. Male and Female patients 50 years old or older
2. Symptomatic peripheral artery disease;For other inclusion criteria see protocol page 31.

Exclusion criteria

1. Patients needing dual anti-platelet drug treatment before start of study
2. Planned revascularisation or amputation
3. Patients with known bleeding disorders
4. Patients with a history of intracranial bleed
5. Patients considered to be at risk of bradycardic events unless already treated with a permanent pacemaker;For other exclusion criteria see protocol page 31-33.

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2013
Enrollment:	225
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Brilique
Generic name:	Ticagrelor
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Plavix
Generic name:	Clopidogrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-11-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	14-12-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	16-05-2013

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-08-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-08-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-08-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-09-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-11-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-04-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-05-2015

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	28-08-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	16-09-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-01-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-01-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2011-004616-36-NL
CCMO	NL41301.058.12