A clinical trial comparing treatment with cangrelor (in combination with usual care) to usual care, in subjects who require percutaneous coronary intervention

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The primary objective of this study is to demonstrate that the efficacy of cangrelor (combined with usual care) is superior to that of usual care, in subjects requiring percutaneous coronary intervention (PCI) as measured by a composite of all-cause...

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

Summary

ID

NL-OMON30625

Source
ToetsingOnline

Brief title
Champion Platform

Condition

- Myocardial disorders

Synonym
Acute coronairy syndroom, Heart diseases

Research involving
Human

Sponsors and support

Primary sponsor: Quintiles
Source(s) of monetary or material Support: The Medicines Company;8 Campus Drive;Parsippany;USA

Intervention

Keyword: Cangrelor, clopidogrel, Percutaneous coronay intervention (PCI), platelet inhibition

Outcome measures

Primary outcome

Primary endpoint:

The primary efficacy endpoint is a composite incidence of all-cause mortality,

MI, and IDR assessed

48 hours after randomization.

Secondary outcome

Secondary endpoints:

• Incidence of :

- all-cause mortality and MI at 48 hours

- all-cause mortality and MI at 30 days

- all-cause mortality, MI and IDR at 30 days

• Individual incidence of components of the composite (all-cause mortality, MI,

and IDR)

at 48 hours and 30 days

• Incidence of stroke, distinguished by type, at 48 hours

• Incidence of abrupt closure, threatened abrupt closure, need for urgent

coronary artery bypass graft

(CABG) surgery, or unsuccessful procedure during the index PCI

• Incidence of all-cause mortality at 6 months (ascertained at the 1 year

follow-up) and 1 year

Study description

Background summary

Each year, over one million patients undergo diagnostic coronary angiography and are discovered to have flow-limiting atherosclerotic plaques that may be amenable to PCI. Complications of PCI, and coronary stenting in particular, are well characterized and include death, myocardial infarction (MI), and the need for emergent or urgent repeat revascularization. A number of pre-procedural treatment strategies using anti-thrombotic therapies have
evolved in an attempt to lower the rate of complications related to performance of PCI. Clopidogrel has become the accepted thienopyridine for
clinical use in the post-stent setting because of its more favorable side effect profile. It is clear that usual care for patients undergoing PCI incorporates clopidogrel therapy based on convincing data revealing improved clinical outcomes when treatment is
instituted immediately after PCI. However, there is ongoing
debate about the optimal timing of clopidogrel administration, and the appropriate
loading dose, given some suggestive but incomplete data on the benefits of pre-treatment
Clopidogrel is a prodrug and must be metabolized by the liver in order to generate the active metabolite. As a result there is a
considerable delay in achieving platelet inhibition following oral administration.
Furthermore, the binding of the active metabolite irreversible, and
new platelets must be generated in order to reverse the drug*s effect.
The potential benefits of Cangrelor in comparison to Clopidogrel before, and during the PCI procedure are the following: Cangrelor works directly after infusion, because the drug is not metabolized in the liver, the effect is reversible, and it works in 100% of the patient population.

Study objective

The primary objective of this study is to demonstrate that the efficacy of cangrelor (combined with usual care) is superior to that of usual care, in subjects requiring percutaneous coronary intervention (PCI) as measured by a composite of all-cause mortality, myocardial infarction (MI), and ischemia

driven revascularisation.

Study design

This is a multicentre phase3 , prospective, randomized, double-blind, placebo-controlled, with parallel groups.

Intervention

De patients receive a 2 hour infusion Cangrelor 30 µg/kg intravenous (IV) bolus + 4 µg/kg/minute IV infusion, or placebo IV bolus and infusion, followed by the standard treatment with Clopidogrel (600mg directly after PCI/infusion followed by 1 year Clopidogrel 75 mg/dag

Study burden and risks

The most common side effects reported to date include:
• hematoma (a collection of blood in the tissues) bruising
• bruising at the infusion puncture site
• stomach discomfort
• back pain
• chest pain
As a medication that affects the function of blood platelets , bleeding can occur at or into any place in the body including:
• into the urine
• at the site of needle sticks
• in the respiratory system

Bleeding events may be severe and result in other complications that may be long term, including death.

Contacts

Public
Quintiles

Siriusdreef 10
2132 WT Hoofddorp
Nederland
Scientific
Quintiles

Siriusdreef 10
2132 WT Hoofddorp

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnostic coronary angiography demonstrating atherosclerosis (excluding ST segment-elevation) amenable to treatment by PCI with or without stent implantation

Exclusion criteria

ST- Elevated MI patients who undergo PCI

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2007
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cangrelor
Generic name:	NvT

Ethics review

Approved WMO Date:	21-09-2006
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	24-11-2006
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	19-06-2007
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	06-09-2007
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	02-10-2007
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO	

Date:	18-10-2007
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	13-03-2008
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	10-06-2008
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	07-04-2009
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	EUCTR2006-003935-56-NL
CCMO	NL13979.094.06