The influence of omeprazole and pantoprazole on the platelet reactivity and inhibition of platelet aggregration of clopidogrel.

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To study the influence of omeprazole and pantoprazole on the platelet reactivity index and the inhibition of platelet aggregation by clopidogrel.

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

Summary

ID

NL-OMON32694

Source
ToetsingOnline

Brief title
The influence of omeprazole and pantoprazole on the activity of clopidogrel

Condition

- Coronary artery disorders
- Gastrointestinal ulceration and perforation

Synonym
Activity of clopidogrel, prophylaxis against NSAID induced gastric damage

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum

Source(s) of monetary or material Support: Afdelingen Klinsche Farmacie en Klinische Chemie van het Atrium MC Parkstad.

Intervention

Keyword: Clopidogrel, Omeprazole, Pantoprazole

Outcome measures

Primary outcome

1. The platelet reactivity index

2. The inhibition of platelet aggregation

Secondary outcome

Side effects of pantoprazole.

Study description

Background summary

Retrospective epidemiological studies showed a higher incidence of cardiovascular events to be associated with the use of clopidogrel in combination with omeprazole. This association is not found for pantoprazole.

Study objective

To study the influence of omeprazole and pantoprazole on the platelet reactivity index and the inhibition of platelet aggregation by clopidogrel.

Study design

Single-center, open-label, cohort study.

Intervention

Replacing of omeprazole by pantoprazole for 4 weeks.

Study burden and risks

The risks are:

complications during the 2 venapunctions (visit 1: 15 ml blood, visit 2: 9 ml blood).
Side effects of pantoprazole.

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. Use of clopidogrel and aspirin or carbasalate calcium.
2. Use of omeprazole as prophylaxis against NSAID induced gastric damage.
3. Written informed consent.
4. 18 years or older.

Exclusion criteria

1. Use of medication which affects the metabolism of clopidogrel
2. Severe adverse reaction or hypersensitivity reaction to pantoprazole.
3. Gastrointesnital ulcer.
5. Renal impairment (creatinine> 200 mmol/l).
6. liver disease (AST, ALT, GGT> 3 x ULN).
7. Pregnancy

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2010
Enrollment:	27
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Pantozol
Generic name:	Pantoprazol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	25-01-2010
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2009-016983-36-NL
CCMO	NL30410.096.09