Effect of Clopidogrel (Plavix) on Postoperative Bleeding in Patients undergoing Coronary Artery Bypass Surgery. A prospective randomized controlled study.

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To investigate if the interruption of the clopidogrel is necessary before CABG in order to prevent bleeding and other complications, and if so, which is the safe time interval to proceed with surgery. To asses the predictive value of the TEG clot...

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

Summary

ID

NL-OMON29792

Source
ToetsingOnline

Brief title
Plavix study

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Fabrikant van clopidogrel (Sanofi-Aventis),Sanofi-aventis

Intervention

Keyword: CABG, Clopidogrel, post-operative bleeding

Outcome measures

Primary outcome

Blood loss, transfusions and rethoracotomies.

Predictive value of TEG

Secondary outcome

Death, myocardial infarction, stroke, respiratory failure, renal failure

requiring dialysis, mediastinitis, wound infection, readmission rates within 30

days from discharge, and ICU and hospital lengths of stay

Study description

Background summary

By blockade of the platelet ADP receptor, clopidogrel inhibits the binding of fibrinogen to the platelet GPIIb/IIIa receptor complex, thereby preventing platelet aggregation from ADP stimulation.

Some authors suggest that the platelet function is completely recovered in 7 days after stopping clopidogrel in healthy subjects. Other researches suggest full recovery of platelet function in 3 to 5 days.

In previous studies, mainly retrospective, it is suggested that the risk of bleeding, blood transfusion and rethoracotomies due to defective coagulation and platelet dysfunction is increased.

In a recent prospective randomized trial it has been demonstrated that the strategy of continuing aspirin and clopidogrel therapy in combination with

intraoperative aprotinine leads to decrease blood loss and blood transfusion requirement compared with stopping therapy with clopidogrel 5 days before surgery.

This finding indicates that surgery does not have to be delayed for this group of patients.

For a more specific determination of coagulation abnormality we will use thromboelastogram (TEG) measurements. These measurements, correlated with the post- surgical blood loss and use of blood products, will help us to asses the predictive value of the TEG clot strength in postoperative bleeding in patients using Clopidogrel.

Study objective

To investigate if the interruption of the clopidogrel is necessary before CABG in order to prevent bleeding and other complications, and if so, which is the safe time interval to proceed with surgery. To asses the predictive value of the TEG clot strength in postoperative bleeding in patients using Clopidogrel.

Study design

A prospective, randomized mono- center study

Study burden and risks

In this trial no changes are made to the standard treatment and care of the patient. Only 1 additional venapunction will be made pre-operatively. Since there are many procedures with respect to the cancellation of clopidogrel before surgery, we assume that there are no additional risks when participating in this trial.

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 who are using clopidogrel at least 5 days before surgery with a dose of 75mg clopidogrel without loading dose, with or without concomitant use of aspirin. Or patients who received a loading dose of 300-600mg clopidogrel 24 hours before CABG, with or without concomitant use of aspirin

Exclusion criteria

concomitant use of coumarine/heparine derivates; pre-existing bleeding disorders; thrombocytopenia; renal and hepatic failure; end-stage heart failure; emergency bypass surgery; concomitant valvular or other cardiac procedures; re-operation; off-pump CABG

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2006
Enrollment:	150
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	23-05-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL11435.060.06