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

Published: 23-05-2006 Last updated: 20-06-2024

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 reviewApproved WMOStatusRecruitment stoppedHealth condition typeCoronary artery disordersStudy typeObservational 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**

#### **Public**

Catharina-ziekenhuis

Michelangelolaan 2 5623 EJ Eindhoven Nederland

## **Scientific**

Catharina-ziekenhuis

Michelangelolaan 2

3 - Effect of Clopidogrel (Plavix) on Postoperative Bleeding in Patients undergoing ... 24-05-2025

# **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