

# An Exploratory, Multi-center, Open-Label, Single-Arm study to evaluate the Discontinuation Effect of Clopidogrel After Drug Eluting Stent (DECADES) on Inflammatory and Platelet Activation Markers in Subjects Who Are Receiving Low Dose Acetylsalicylic Acid (ASA)

Published: 03-09-2007

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Primary Objective: To assess whether the withdrawal of clopidogrel 12 months after Drug Eluting Stent (DES) implantation leads to an increase in markers of inflammation and platelet activation. Secondary Objectives: To assess the withdrawal of...

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

## Summary

### ID

NL-OMON31060

### Source

ToetsingOnline

### Brief title

CV149-208

### Condition

- Coronary artery disorders
- Vascular disorders NEC

### Synonym

subjects with one or more drug eluting stents

## **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Bristol-Myers Squibb

**Source(s) of monetary or material Support:** Pharmaceutical Industry- Bristol-Myers Squibb

## **Intervention**

**Keyword:** clopidogrel, inflammation, platelet activation, stent

## **Outcome measures**

### **Primary outcome**

Assess the mean change in the level of soluble CD40 Ligand over a four week follow up period following withdrawal of clopidogrel after a 12 month treatment period.

### **Secondary outcome**

1. Changes in levels of high sensitivity C-reactive protein (hs-CRP) and plasma soluble P-selectin.
2. Safety (evaluated by Adverse Event/Serious Adverse Event (AE/SAE) reports).

## **Study description**

### **Background summary**

Beginning in late 2006, there has been increasing awareness of an increased incidence of stent thrombosis occurring many months after implantation of DES. Although the exact frequency of this event remains controversial and the cause may be multifactorial, enough instances have been associated with premature discontinuation of effective antiplatelet therapy with ASA and clopidogrel that the American Heart Association et al. issued an advisory on 16 January 2007 recommending that \*patients who have had drug eluting stents inserted to prop open blocked coronary arteries should continue to take medications to reduce

the risk of blood clots for at least one year after the stent is inserted\*. This recommendation has been echoed by other professional cardiology associations in North America and Europe. Therefore this study has been developed to evaluate the effect of clopidogrel withdrawal 12 months after DES.

## **Study objective**

Primary Objective: To assess whether the withdrawal of clopidogrel 12 months after Drug Eluting Stent (DES) implantation leads to an increase in markers of inflammation and platelet activation.

Secondary Objectives:

To assess the withdrawal of clopidogrel 12 months after DES implantation on:

- Laboratory biomarkers: Plasma soluble P-selectin, High sensitive C-reactive protein (hs-CRP)
- Safety measures: Adverse Events (AE) / Serious Adverse Events (SAE) reports.

## **Study design**

Exploratory, multi-center, open-label, single-arm study. Patients will have a screening visit at the end of their 12 months of clopidogrel treatment and have 4 follow-up visits in 4 weeks.

## **Study burden and risks**

This is an exploratory study. Subjects will be treated as per routine practice, having their clopidogrel treatment withdrawn 12 months after its initiation at the time of DES implantation. ASA monotherapy will be continued. The risks to the study subjects are solely those associated with routine weekly blood draws over a period of 4 weeks. There will be a total of 5 blood draws during the subject's participation in the study.

## **Contacts**

### **Public**

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### **Scientific**

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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. Subjects with one or more sirolimus or paclitaxel drug-eluting stents who are coming to the end of their 12 months of clopidogrel (75 mg daily) treatment.
2. Subjects receiving low dose ASA.
3. Subjects receiving a statin.
4. Current medication regimen (including ASA and statins) must have been stable for three (3) months, i.e. no initiation of new prescription medication or change in dosage of any previously initiated medication within three (3) months of entering this study.
5. Subjects with no clinical history of diabetes mellitus.

### **Exclusion criteria**

1. Subjects with a clinical history of diabetes mellitus.
2. History of alcohol or substance abuse within the past 12 months.
3. Any condition the Investigator believes would interfere with evaluation of the subject or which could put the subject at undue risk.
4. Uncontrolled hypertension (systolic blood pressure >180mmHg or diastolic >100mmHg) at screening.
5. Intolerance or contraindication to ASA or statins.
6. Current use or use within the past 3 months of oral anticoagulants or dipyridamole or oral glucocorticoids.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 31-10-2007

Enrollment: 25

Type: Actual

## Ethics review

Approved WMO

Date: 03-09-2007

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL18236.078.07
Other	volgt, aanvraag loopt