# Effect of clopidogrel and acetylsalicylic acid (ASA) versus clopidogrel or ASA alone on brachial flow mediated vasodilation in patients with coronary artery disease

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
13/12/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/01/2010	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/05/2011	Circulatory System			

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Ascan Warnholtz

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

Effect of clopidogrel and acetylsalicylic acid (ASA) versus clopidogrel or ASA alone on brachial flow mediated vasodilation in patients with coronary artery disease: a prospective, double-blind, randomised, single-centre trial

#### Acronym

**CASSANDRA** 

#### Study objectives

Treatment with clopidogrel 75 mg per day improves brachial artery flow-mediated dilation of patients with coronary artery disease.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Local ethics committee (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz) approved on the 20th December 2004

#### Study design

Prospective double-blind randomised single-centre three-armed phase IV clinical trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

# Health condition(s) or problem(s) studied

Stable coronary artery disease

#### Interventions

Clopidogrel 75 mg per day versus clopidogrel 75 mg and acetylsalicylic acid 100 mg per day versus acetylsalicylic acid 100 mg per day for 4 weeks.

# Intervention Type

#### Phase

Phase IV

## Drug/device/biological/vaccine name(s)

Clopidogrel, acetylsalicylic acid (ASA)

#### Primary outcome measure

Effect of treatment on the absolute change in % flow-mediated dilation (FMD) of the right brachial artery. Evaluated by measurements at the beginning of the trial and at the end of treatment at day 28.

#### Secondary outcome measures

Effects of treatment on:

- 1. Platelet superoxide production
- 2. Adenosine diphosphate (ADP)-induced platelet aggregation
- 3. Nitroglycerin-induced brachial artery dilation
- 4. Inflammatory markers

Evaluated by measurements at the beginning of the trial and at the end of treatment at day 28.

#### Overall study start date

10/04/2006

#### Completion date

06/06/2007

# **Eligibility**

#### Key inclusion criteria

- 1. Men or women, older than 18 years of age
- 2. Angiographically documented coronary artery disease
- 3. Absence of angina pectoris within the previous four weeks
- 4. Written informed consent must be available before enrolment in the trial

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

120

#### Key exclusion criteria

- 1. Stroke or peripheral arterial revascularisation within the previous 12 weeks
- 2. Clopidogrel intolerance
- 3. Planned coronary stent implantation within the next 6 weeks
- 4. Haemodynamically significant valvular heart disease
- 5. Known hyper- or hypothyroidism
- 6. Renal dysfunction (creatinine more than 2.0 mg/dl)
- 7. Chronic inflammatory intestinal disease or history of malabsorption
- 8. History of chronic liver disease or pancreatitis
- 9. Existence of acute gastric ulcers or acute gastrointestinal bleeding
- 10. Haemoglobin less than 12 g/dl, white blood cells (WBC) less than 4/nl or platelet count less than 100/nl
- 11. History of organ transplantation
- 12. Anticipated non-compliance with the protocol
- 13. Pregnancy
- 14. Participation in another clinical trial
- 15. Clinical signs of congestive heart failure or left ventricular ejection fraction less than 40%
- 16. Uncontrolled hypertension (blood pressure more than 180/105 mmHg)
- 17. Orthostatic hypotension (supine systolic blood pressure less than 90 mmHg)
- 18. Treatment with clopidogrel or ticlopidine within the last 28 days prior to study start
- 19. Initiation of treatment with angiotensin converting enzyme (ACE) inhibitor, statin or calcium channel blocker within previous 2 weeks

#### Date of first enrolment

10/04/2006

#### Date of final enrolment

06/06/2007

# Locations

#### Countries of recruitment

Germany

# Study participating centre Department of Medicine II

Mainz Germany 55131

# Sponsor information

#### Organisation

Johannes Gutenberg-University Mainz (Johannes Gutenberg-Universitat Mainz) (Germany)

#### Sponsor details

Langenbeckstrasse 1 Mainz Germany 55101

# Sponsor type

University/education

#### Website

http://www.klinik.uni-mainz.de/2-Med/

#### **ROR**

https://ror.org/023b0x485

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Bristol-Myers Squibb GmbH & Co. KGaA (Germany)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011		Yes	No