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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Drug

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
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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