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Effect of clopidogrel loading dose on brachial flow mediated vasodilation in patients with coronary artery disease

Submission date 30/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/12/2006	**Overall study status** Completed	
Last Edited 06/01/2021	**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 loading dose on brachial flow mediated vasodilation in patients with coronary artery disease

Acronym
CLEOPATRA

Study objectives
One single dose of clopidogrel causes dose-dependent improvement of flow-mediated dilation to the right brachial artery in patients with stable coronary artery disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz), dated Dec 20th, 2004 (ref: 837.473.04 [4631]).

Study design
A prospective, double-blind, randomised, single-center, two-armed clinical trial of phase IV.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Stable coronary artery disease

Interventions
Single dose of 300 mg versus 600 mg of clopidogrel orally.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)

Clopidogrel

Primary outcome measure
Effect of treatment on the absolute change in % Flow-Mediated Dilation (FMD).

Secondary outcome measures
Effects of treatment on:
1. Platelet superoxide production
2. Platelet basal VAsodilator-Stimulated Phosphoprotein (VASP)-phosphorylation
3. Platelet P2V12-receptor inhibition

Overall study start date
01/03/2005

Completion date
02/02/2006

Eligibility

Key inclusion criteria
1. Men or women, older than 18 years of age
2. Angiographically documented, clinically stable coronary artery disease (defined as at least one coronary artery stenosis more than 50% or general wall irregularities)
3. Endothelial dysfunction, defined as a Flow-Mediated Vasodilatation (FMD) of less than 8%
4. Ability of subject to understand character and individual consequences of clinical trial
5. Written informed consent must be available before enrolment in the trial
6. Current therapy with acetylsalicylic acid 100 mg/d

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
58

Total final enrolment
58

Key exclusion criteria
1. Acute coronary syndrome
2. Clinical signs of congestive heart failure or left ventricular ejection fraction less than 40%
3. Uncontrolled hypertension (blood pressure more than 180/105 mmHg) or hypotension

(systolic blood pressure less than 90 mmHg)
4. Treatment with clopidogrel or ticlopidine within the last 28 days prior to study start
5. Haemodynamically significant valvular heart disease
6. Renal dysfunction (creatinine more than 2.0 mg/dl)
7. History of chronic liver disease or pancreatitis
8. Alcohol abuse
9. Haemoglobin less than 12 g/dl, White Blood Cells (WBC) less than 4/nl or platelet count less than 100/nl
10. Existence of acute gastric ulcers or acute gastrointestinal bleeding
11. Chronic inflammatory intestinal disease or history of malabsorption
12. Known hyper- or hypothyroidism
13. Anticipated non-compliance with the protocol
14. Pregnancy
15. Participation in another clinical trial

Date of first enrolment
01/03/2005

Date of final enrolment
02/02/2006

Locations

Countries of recruitment
Germany

Study participating centre
Johannes Gutenberg-Universität Mainz
Mainz
Germany
55101

Sponsor information

Organisation
Johannes Gutenberg-Universität Mainz (Germany)

Sponsor details
c/o Prof. Dr. T. Münzel
Department of Medicine II
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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	01/02/2008	06/01/2021	Yes	No