

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
Registration date 06/12/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/01/2021	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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]).

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Effects of treatment on:

1. Platelet superoxide production
2. Platelet basal VASodilator-Stimulated Phosphoprotein (VASP)-phosphorylation
3. Platelet P2V12-receptor inhibition

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/023b0x485>

Funder(s)

Funder type

Industry

Funder Name

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

Results and Publications

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