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

Submission date	Recruitment status	Prospectively registered
30/11/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
06/12/2006	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
06/01/2021	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

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 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	01/02/2008	06/01/2021	Yes	No