

Effect of 8 weeks oral pentaerithrityltetranitrate on endothelial dysfunction in patients with coronary artery disease: a prospective, randomized, double-blind, placebo-controlled, monocentric clinical trial of phase IV

Submission date 29/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 07/06/2007	Overall study status Completed	
Last Edited 07/01/2020	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
2006-004533-15

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effect of 8 weeks oral pentaerithrityltetranitrate on endothelial dysfunction in patients with coronary artery disease: a prospective, randomized, double-blind, placebo-controlled, monocentric clinical trial of phase IV

Acronym

PENTA

Study objectives

Eight weeks of oral pentaerithrityltetranitrate therapy in addition to standard long-term Coronary Artery Disease (CAD) medication improves flow dependent vasodilation (FMD) in patients suffering from CAD.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the physicians chamber of Rhineland-Palatinate (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz), approved on 21.03.2007.

Study design

A prospective, placebo-controlled, double-blind, randomized, parallel group, single center, two-armed, clinical trial of phase IV

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Coronary artery disease

Interventions

Eight weeks of pentaerithrityltetranitrate, 80 mg, 3 x orally per day.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

pentaerithrithyl tetranitrate

Primary outcome measure

FMD at baseline and after 8 weeks of treatment, measured by high-resolution ultrasound of the right brachial artery diameter percentage change upon reactive hyperemia after 5 minutes suprasystolic occlusion of the upper arm.

Secondary outcome measures

The following will also be assessed at baseline and after 8 weeks of treatment:

1. Cardiovascular biomarkers (high-sensitivity C-Reactive Protein [hs-CRP], lipid profile, ferritin, bilirubin, uric acid)
2. Endothelium-independent nitroglycerin-induced vasodilation (NMD)
3. Endo-PAT2000 (device for assessing endothelial function) reactive hyperemia index

Overall study start date

01/06/2007

Completion date

31/05/2008

Eligibility**Key inclusion criteria**

1. Men or women > 35 and < 80 years of age
2. Documented clinically stable CAD with stable angina pectoris
3. Ability of subject to understand the character and individual consequences of the clinical trial
4. Written informed consent must be available before enrollment in the trial
5. For women with childbearing potential, adequate contraception (oral contraceptives or intrauterine devices) is required

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80 subjects, 40 per treatment group

Total final enrolment

Key exclusion criteria

1. Clinical signs of congestive heart failure or left ventricular ejection fraction <30% (as demonstrated within the last 1 year by echocardiography, Left Ventricular [LV] angiography, Magnetic Resonance Imaging [MRI] or radionuclide ventriculography, respectively)
2. Uncontrolled hypertension (blood pressure >180/110mmHg) or hypotension (systolic blood pressure <110 mmHg)
3. Initiation of any of the following medications within the last 8 weeks: aspirin, statins, calcium antagonists, Angiotensin Converting Enzyme (ACE)-inhibitors or AT1 receptor blockers, hormone replacement therapy. Individuals who take any of these drugs longer than 8 weeks can be included in this trial.
4. Use of Phosphodiesterase-5-inhibitors (Viagra®, Revatio®, Cialis®, Levitra®), dihydroergotamine and nitrates i.e. isosorbidedmononitrate, isosorbidedinitrate, nitroglycerin, pentaerithrityltetranitrate or molsidomin within the last two weeks.
5. Hemodynamically significant aortic or mitral stenosis or hypertrophic obstructive cardiomyopathy (as demonstrated within the last year by echocardiography, invasive right/ left heart catheterization or MRI, respectively)
6. Renal dysfunction (plasma creatinine [men: > 2.0 mg/dl, women: > 1.8 mg/dl])
7. Known hepatic disease or elevation of serum transaminases or gGT > 3 x Upper Limit of Normal range (ULN)
8. White Blood Cells (WBC) >16.000 or platelet count >500.000/µl or <75.000/µl
9. Clinically overt hyperthyreodism
10. Pregnancy and lactation
11. Known intolerance to organic nitrates
12. Known lactose intolerance
13. History of hypersensitivity to the investigational medicinal product or to any drug with similar chemical structure or to any excipient present in the pharmaceutical form of the investigational medicinal product
14. Other significant laboratory abnormalities that the investigator feels may compromise the patient's safety by participation in the study
15. In other clinical trials and observation period of competing trials, respectively

Date of first enrolment

01/06/2007

Date of final enrolment

31/05/2008

Locations**Countries of recruitment**

Germany

Study participating centre

Langenbeckstr. 1

Mainz

Germany

55131

Sponsor information

Organisation

Johannes Gutenberg University of Mainz (Germany)

Sponsor details

Langenbeckstr. 1

Mainz

Germany

55131

Sponsor type

University/education

Website

<http://www.uni-mainz.de/eng/>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Actavis Germany GmbH & Co KG (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	01/02/2010	07/01/2020	Yes	No