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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

Registration date
07/06/2007

Overall study status
Completed

Last Edited
07/01/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
2006-004533-15

Protocol serial number
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 pentaerithrithyltetranitrate 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

Study type(s)
Treatment

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(s)

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.

Key secondary outcome(s))
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 nitrogylcerin-induced vasodilation (NMD)
3. Endo-PAT2000 (device for assessing endothelial function) reactive hyperemia index

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
80

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. isosorbidemononitrate, 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 catherterization 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)

ROR
https://ror.org/023b0x485

Funder(s)

Funder type
Industry

Funder Name
Actavis Germamy GmbH & Co KG (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	01/02/2010	07/01/2020	Yes	No