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Impact of 12 weeks oral niacin on endothelial function, lipid composition and cardiovascular biomarkers in patients with coronary artery disease: a prospective, randomized, double-blind, placebo-controlled, monocentric clinical trial of phase IV

Submission date	Recruitment status	[_] Prospectively registered
13/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/07/2014	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
INEF

Study information

Scientific Title

Acronym
INEF

Study objectives
Twelve weeks oral niacin 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-commission of the country physicians chamber Rhineland-Palatinate (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz)

Study design
Prospective placebo-controlled double-blind randomized parallel-group single-center two-armed clinical phase IV trial

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 (CAD) and known dyslipidemia

Interventions
Twelve weeks oral Niacin therapy

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Niacin

Primary outcome measure
Effect of 12 weeks oral niacin therapy in addition to standard long-term CAD medication on flow dependent vasodilation (FMD) in patients suffering from CAD

Secondary outcome measures
Effects of niacin therapy on plasma lipid composition, HDL-C levels, LDL, triglycerides, total cholesterol, cholesterol ratio, high sensitivity C-reactive protein (hs-CRP), cardiovascular biomarkers, endothelium-independent nitrogylcerin-induced vasodilation (NMD) and FMD levels.

Overall study start date
19/01/2006

Completion date
19/05/2006

Eligibility

Key inclusion criteria
1. Men or women > 35 and < 80 years of age
2. Documented clinically stable CAD and known dyslipidemia, defined by a low-density lipoprotein cholesterol (LDL >70 mg/dl) and a high density lipoprotein cholesterol (HDL <65mg /dl)
3. 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. For women with childbearing potential, adequate contraception

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100 subjects, i.e. 50 subjects per treatment group

Key exclusion criteria
1. Clinical signs of congestive heart failure or left ventricular ejection fraction <30%
2. Uncontrolled hypertension (blood pressure >180/110mmHg) or hypotension (systolic blood pressure <90 mmHg)

3. Initiation of any of the following medications within the last twelve weeks: aspirin, lipid-lowering agents, calcium antagonists, betablockers, angiotensin converting enzymes inhibitors (ACEI) or angiotensin 1 (AT1) receptor blockers, hormone replacement therapy
4. Use of steroids or chemotherapy drugs within the past year or chronic use of non-steroidal anti-inflammatory drugs except for aspirin
5. Hemodynamically significant valvular heart diseases or hypertrophic obstructive cardiomyopathy
6. Renal dysfunction (creatinine > 2.5 mg/dl)
7. Known hepatic disease or elevation of serum transaminases or gamma glutamyl transferase (gGT) > 2x ULN (upper limit of normal range)
8. Uric acid >10.0 mg/dl
9. Alcohol abuse
10. White blood cell (WBC) count >12,000 or platelet count >500,000 /ul or <75,000 /ul
11. Existence of acute gastric ulcers
12. Existence of acute arterial bleeding
13. Other significant laboratory abnormalities

Date of first enrolment
19/01/2006

Date of final enrolment
19/05/2006

Locations

Countries of recruitment
Germany

Study participating centre
Johannes Gutenberg-University Mainz
Mainz
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Sponsor information

Organisation
Johannes Gutenberg-University Mainz (Germany)

Sponsor details
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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
Merck Pharma GmbH

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	01/05/2009		Yes	No