

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 13/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/01/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/07/2014	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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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 nitroglycerin-induced vasodilation (NMD) and FMD levels.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Germany

55131

Sponsor information

Organisation

Johannes Gutenberg-University Mainz (Germany)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Merck Pharma GmbH

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	01/05/2009		Yes	No