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Mono-centred, randomised, placebo-controlled, double-blind parallel-arm study on the effect of Conjugated Linoleic Acid (CLA) on endothelial function and (postprandial) metabolic parameters in overweight men

Submission date 03/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/10/2008	**Overall study status** Completed	
Last Edited 03/01/2012	**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

Protocol serial number
N/A

Study information

Scientific Title

Acronym
CLA1

Study objectives
Conjugated linoleic acid (CLA) may beneficially affect lipid and glucose metabolism, inflammatory responses and body weight. These aspects are of relevance for subjects afflicted with or prone to develop a so-called metabolic syndrome, which is characterised by an insulin resistance, dyslipidaemia, essential hypertension and adiposity of the central type and frequently leads to early manifestation of type 2 diabetes mellitus, increased vascular risk and risk of atherosclerosis. This study examines the influence of dietary conjugated linoleic acid (CLA) (commercially available 50:50 mixture of isomers cis9,trans11-CLA and trans10,cis12-CLA) on endothelial function and below mentioned fasting and postprandial metabolic parameters in comparison to safflower oil. For explorative purposes two more groups are given native olive oil or heated (thermally oxidised) safflower oil. Tocopherol concentration of the supplements is adjusted to that of safflower oil. Further parameters to judge pro-atherogenic processes are soluble adhesion molecules (intercellular adhesion molecule [ICAM], vascular cell adhesion molecule [VCAM], E-Selectin) which promote inflammatory processes by initiating the adherence of leukocytes and monocytes to the endothelium of blood vessels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the Medical Faculty of the Christian-Albrechts-University of Kiel (Germany) on the 13th April 2006 (ref: A 106/06)

Study design
Single centre, randomised double-blind placebo-controlled intervention study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Group 1: CLA 50:50 isomer mixture (cis9,trans11-CLA: trans10,cis12-CLA)
Group 2: safflower oil
Group 3: native olive oil
Group 4: safflower oil - thermally oxidised

Supplements given two times a day during breakfast (or lunch) and dinner, four capsules each, making a total dose per day of eight capsules (= 4.5 g). Total duration of treatment was 4 weeks (28 + 2 days), for all four treatments.

Follow up:
Start of the follow up period, i.e. start of the intervention for the first study subjects was 24/04 /2006. End of the trial follow-up period was 02/08/2006.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Conjugated linoleic acid (CLA), safflower oil, native olive oil

Primary outcome(s)
Changes in endothelial function: PAT-Index after 28(± 2) days supplementation.

Key secondary outcome(s))
1. Body mass index (BMI)
2. Waist circumference (WC)
3. Waist to hip ratio (WHR)
4. Blood pressure, pulse

Changes in:
5. Fasting and postprandial triglycerides (AUC)
6. Fasting and postprandial insulin (AUC)
7. Fasting and postprandial glucose (AUC)
8. Homeostasis model assessment of insulin resistance (HOMA-IR) (insulin-glucose-product)
9. HOMA-b-cell-function
10. Lipids, namely total, low density lipoprotein (LDL-) and high density lipoprotein (HDL-) cholesterol
11. Oxidative modification of lipids and oxidative stress, namely: oxidised LDL, isoprostanes
13. Inflammatory parameters, namely: C-reactive protein (CRP), soluble vascular cell adhesion molecule (sVCAM), soluble intercellular adhesion molecule (sICAM), soluble E-selectin, interleukin-6 (IL-6), tumour necrosis factor alpha (TNF alpha), monocyte chemoattractant protein-1 (MCP-1)
14. Other regulators/hormones: adiponectin, leptin, ghrelin, glucagon-like peptide 1 (GLP-1), cholecystokinin (CCK), vascular endothelial growth factor (VEGF)

All secondary parameters were determined both at start of the intervention (day 0) and end of the study, i.e. after 4 weeks. Treatment-induced changes were calculated and compared between intervention groups.

Completion date
02/08/2006

Eligibility

Key inclusion criteria
1. Healthy male volunteers
2. Aged 45 - 68 years
3. Body mass index (BMI) 25 - 29 kg/m^2
4. Member of the Metabolic Intervention Cohort Kiel (MICK)
5. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Participation in a clinical study with a medicament or a medicinal product within the last 30 days or simultaneous participation in another clinical examination
2. Inability to understand and to comply with the study protocol
3. Known metabolic or gastro-intestinal diseases, which affect the absorption, metabolism or excretion of food or food components
4. Condition after surgery of the gastro-intestinal tract, which affects gastro-intestinal motility
5. Haemoglobin less than 12 g/dL
6. Latex allergy
7. Diabetes (fasting glucose levels greater than 125 mg/dl after repeated determination)
8. Surgery within the last 3 months, which still affects the current state of health
9. Intake of nitrate and/or calcium antagonists, which affect the blood pressure
10. Deformation of finger tips, which inhibits correct recording of EndoPAT (measures a Peripheral Arterial Tone [PAT™] signal for assessment of endothelial dysfunction)
11. Illness of thyroid gland, which has metabolic and/or cardiovascular effect
12. Known hepatitis B, hepatitis C, human immunodeficiency virus (HIV) infection or chronic liver disease
13. Kidney malfunction
14. Psychiatric disorders, epilepsy, risk of suicide
15. Drug or alcohol abuse
16. Intake of drugs affecting the absorption, metabolism or excretion of food components or the gastro-intestinal motility
17. Intake of hormone preparations, particularly cortisone
18. Eating disorders, anorexia, bulimia, unusual outsider dietary habits
19. Legal incapacity
20. Others depending on the judgement of the study physician

Date of first enrolment
18/04/2006

Date of final enrolment
02/08/2006

Locations

Countries of recruitment
Germany

Study participating centre
Max Rubner-Institute
Kiel
Germany
24103

Sponsor information

Organisation
Max Rubner Institute (Germany)

ROR
https://ror.org/045gmmg53

Funder(s)

Funder type
Government

Funder Name
Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung [BMBF]) (Germany)

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Federal Ministry of Food, Agriculture and Consumer Protection (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz) (Germany)

Funder Name
Cognis GmbH (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	01/02/2011		Yes	No