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Randomised, controlled, double-blind clinical study on the effect of a functional milk-product on metabolism of men with diagnosed metabolic syndrome

Submission date 01/03/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/04/2007	**Overall study status** Completed	
Last Edited 21/09/2007	**Condition category** Nutritional, Metabolic, Endocrine	

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

N/A

Study information

Scientific Title

Acronym
EFOMS (Effect of Functional milk product On the Metabolic Syndrome)

Study objectives
The goal of the investigation is the question, to what extent the risk of the metabolic syndrome may be reduced by substances naturally occurring in milk. The pathophysiology of the metabolic syndrome is characterized by an insulin resistance, a dyslipidaemia, an essential hypertension and adiposity of the central type and frequently leads to early manifestation of type 2 diabetes mellitus and atherosclerosis. Such metabolic disturbances increase in the industrialized countries and in the developing countries, too, and represent an important economical and public-health cost factor. It is necessary to identify the relevant factors of human nutrition and to develop potential avoidance strategies, e.g. by development of functional food. The cow-milk derived substances, which will be used in this study have had influenced individual components of the metabolic syndrome and lowered the risk of components of the metabolic syndrome in an animal trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethic committee of the medical faculty of the Christian-Albrechts-University of Kiel, (Germany), approved on 09.01.2007, Ref: A171/06

Study design
The study is a randomised double-blind placebo-controlled intervention study over 8 weeks

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
Metabolic syndrome

Interventions
The volunteers of the verum group will take one portion of the functional milk-product (product code 966125, a non-registered product) once a day after lunch with a dessert for 56 days. The product of the control group is based on meat protein and is isoenergetic and isonitrogenous.

Primary and secondary outcome measures will be analysed before and at the end of the intervention.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
milk product

Primary outcome measure
Change of blood fructosamine concentration during the intervention period

Secondary outcome measures
1. Insulin sensitivity
2. Endothelial function
3. Blood pressure
4. Waist-to-hip ratio
5. Postprandial concentration of several hormones and blood parameters linked to fat and carbohydrate metabolism

Overall study start date
05/02/2007

Completion date
23/05/2007

Eligibility

Key inclusion criteria
Men, 45-70 years old, with a metabolic syndrome as defined by the International Diabetes Federation, 2006 (A new IDF worldwide definition of the metabolic syndrome: the rationale and the results - Diabetes Voice, Vol. 50 Issue 3, 2005)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60 volunteers (30 for each the verum and control group)

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. Intake of nitrate and/or calcium antagonists and/or alpha-blockers, which affect the blood pressure
3. Known metabolic or gastro-intestinal diseases, which affects the absorption, metabolism or excretion of food or food component
4. Condition after operation of the gastro-intestinal tract, which affect gastro-intestinal motility
5. Hemoglobin < 12 g/dL
6. Malfunction of blood coagulation or drugs, leading to malfunction of blood coagulating diabetes
7. Operation within the last 3 months, which still affects the current state of health
8. Illness of thyroid gland, which has metabolic and/or cardiovascular effect
9. Known hepatitis B, hepatitis C, HIV infection or chronic liver damage
10. Kidney insufficiency
11. Hypercalcaemia
12. Drug or alcohol abuse
13. Intake of drugs affecting the absorption, metabolism or excretion of food components or the gastro-intestinal
14. Intake of hormone preparations
15. Vegetarianism, anorexia, bulimia
16. Known milk protein allergy

Date of first enrolment
05/02/2007

Date of final enrolment
23/05/2007

Locations

Countries of recruitment
Germany

Study participating centre
Hermann-Weigmann-Str. 1
Kiel
Germany
24103

Sponsor information

Organisation

Humana GmbH (Germany)

Sponsor details
Bielefelder Strasse 66
Herford
Germany
32051

Sponsor type
Industry

Website
http://www.humana.de

Funder(s)

Funder type
Industry

Funder Name
Humana GmbH (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