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Effect of Functional milk product On the Metabolic Syndrome II

Submission date	Recruitment status	[ ] Prospectively registered
18/12/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/02/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/02/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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

Acronym
EFOMS II

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 characterised 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 industrialised 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 own animal and human trials.

This study is an extension of a previous human study (ISRCTN41474531 - see http://www.controlled-trials.com/ISRCTN41474531).

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 26th October 2007 (ref: A171/06 - extended sample size).

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)
Hospital

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)
Functional milk-product (product code 966125, a non-registered product)

Primary outcome measure
Change of HOMeostasis model Assessment of Insulin Resistance (HOMA-IR) during the intervention period.

Secondary outcome measures
1. Blood pressure
2. Body mass index (BMI), waist-to-hip ratio
3. Mean blood glucose during continuously glucose monitoring
4. Postprandial concentration of several hormones and blood parameters linked mainly to carbohydrate metabolism

Overall study start date
27/11/2007

Completion date
30/07/2008

Eligibility

Key inclusion criteria
1. Men, 45 - 70 years old
2. 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
Adult

Sex
Male

Target number of participants
240 volunteers (120 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 components
4. Condition after operation of the gastro-intestinal tract, which affect gastro-intestinal motility
5. Haemoglobin less than 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 effects
9. Known hepatitis B, hepatitis C, human immunodeficiency virus (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 tract
14. Intake of hormone preparations
15. Vegetarianism, anorexia, bulimia
16. Known milk protein allergy

Date of first enrolment
27/11/2007

Date of final enrolment
30/07/2008

Locations

Countries of recruitment
Germany

Study participating centre
Institute for Physiology and Biochemistry of Nutrition
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