

# Effect of Functional milk product On the Metabolic Syndrome II

<b>Submission date</b> 18/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 05/02/2008	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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