

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Influence of milk as compared to soy phospholipids on risk factors for cardiovascular disease

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Phospholipids are a class of lipids like cholesterol and triglycerides. They are found in all cells of the body as well as in foods. Phospholipids of milk are rich in phosphatidylcholine and sphingomyelin. Soy phospholipids (phospholipids of plant origin) have a different phospholipid pattern than milk phospholipids. Furthermore their fatty acid pattern is different. They contain primarily polyunsaturated fatty acids, while milk phospholipids are rich in saturated fatty acids.

In this intervention study two groups of overweight or obese men aged 50 to 76 years consume daily 250 ml milk which contains in addition either 3g milk phospholipids or 3g soy phospholipids. At the start and after 7 weeks fasting blood samples are collected and body composition is determined. In blood or plasma various parameters are determined which affect the risk for cardiovascular disease, like total, HDL and LDL cholesterol, triglycerides and glucose. Phospholipids in the diet can inhibit the absorption of cholesterol from the intestine into the blood stream. By this way and through other mechanisms they can modify cholesterol metabolism, as well as hepatic metabolism and inflammatory and antioxidative functions in the body in a favourable way. It is assumed that the fatty acid pattern of phospholipids is only of secondary importance, and that milk phospholipids have a comparable or even better effect on these risk parameters than soy phospholipids.

Brief Summary in Scientific Language

It is assumed that the effect of phospholipids on human and animal metabolism is primarily determined by the phospholipid structure and only secondarily by their fatty acid pattern. Fatty acids given as either triglycerides or phospholipids exert different effects. Phospholipids of the milk fat globule contain more saturated fatty acids than plant phospholipids. These more saturated phospholipids seem to have specific metabolic roles, different from those with more unsaturated fatty acids. Furthermore different phospholipid classes play different metabolic roles. Choline in phosphatidylcholine is a source of methyl groups, and may thus modulate the synthesis of the endogenous antioxidants glutathione and lower the



homocysteine concentration in plasma. Furthermore phospholipids can increase the concentration of apolipoprotein A1 and HDL-cholesterol, additional antiinflammatory mechanisms. In this respect phospholipids with more saturated fatty acids may be more effective. The present study examines the effect of milk phospholipids as compared to soy phospholipids on risk factors for cardiovascular disease (the ratio of total-to-HDL-cholesterol as primary parameter) and various parameters of hepatic metabolism, inflammation and oxidative stress.

Organizational Data

- DRKS-ID: **DRKS00003125**
- Date of Registration in DRKS: **2011/06/09**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **F-2010-089 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **E78.9 - Disorder of lipoprotein metabolism, unspecified**

Interventions/Observational Groups

- Arm 1: **Daily consumption of 250 mL milk, enriched with 3 g milk phospholipids, during 7 weeks**
- Arm 2: **Daily consumption of 250 mL milk, enriched with 3 g soy phospholipids, during 7 weeks**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
-

Study Type: **Interventional**

Study Type Non-Interventional: [---]*

Allocation: **Randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

Control: **Active control (effective treatment of control group)**

Purpose: **Basic research/physiological study**

- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Ratio of total zu HDL-cholesterol in serum (after 7 weeks)

Secondary Outcome

Further parameters of lipid metabolism(triglycerides, LDL-cholesterol), glucose metabolism (glucose, insulin), hepatic metabolism (GOT, GGT, GPT), thiol metabolism (glutathione, homocysteine), inflammation (CRP, endothelial adhesion molecules) and body composition after 7 weeks intervention

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/01/26**
- Target Sample Size: **62**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **50 Years**
- Maximum Age: **76 Years**

Additional Inclusion Criteria

Overweight male volunteers, age 50- 76 years, non-smokers; written informed consent

Exclusion criteria

- **fasting glucose levels >120 mg/dl**
- **Known metabolic or gastro-intestinal diseases, which affect the absorption, metabolism or excretion of food or food components;**
- **Known allergy against milk or soy components**
- **intake of supplements which might affect the parameters tested**
- **intake of drugs which might affect the parameters tested**
- **intestinal tract surgery or corticoid steroid treatment within the last 3 months**
- **Inability to understand and to comply with the study protocol;**
- **unusually high consumption of milk or dairy products**
- **occurrence of acute gastrointestinal disorders during intervention**
- **Occurrence of other unexpected events with relevance for the study outcome**
- **withdrawal of consent to participate**

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

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■ Private sponsorship (foundations, study societies, etc.)

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/06/09**

Trial Publications, Results and other documents

- Paper **Weiland A, Bub A, Barth SW, Schrezenmeir J, Pfeuffer M. Effects of dietary milk- and soy-phospholipids on lipid-parameters and other risk indicators for cardiovascular diseases in overweight or obese men - Two double blind, randomized, controlled, clinical trials. J Nutr Sci 2016; vol. 5, e21, page 1-9. (doi:10.1017/jns.2016.9)**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.