Trial Description

Title

Effect of a dietary supplement with tocotrienols and polymethoxylated flavones (PMF) on serum lipid parameters in probands with hypercholesterolemia and elevated hsCRP levels

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**Influence of a nutritive supplement on hyperlipidemia, specifically LDL-hypercholesterolemia, and elevated inflammatory markers (e.g. high sensitive C-reactive protein). The investigation will be performed in a placebo-controlled double-blind study with three arms. The study sample will include approximately 120 probands with hypercholesterolemia and elevated hsCRP levels, which are not pre-treated with lipid-lowering medications. Probands will be screened for inclusion and exclusion criteria. Additionally, potential probands will be invited for a blood test. Only probands that fulfill inclusion criteria on LDL-Cholesterol (≥ 130 mg/dL) and hsCRP (≥ 2 mg/L) levels will be included in the study sample.
Screening will be at week -2 and intervention time at week 0, week 6 and week 12.
Hypothesis: Decrease of blood lipids (especially LDL-cholesterol) and of inflammatory markers by a nutritive supplement with tocotrienols and flavones compared to placebo.**

Brief Summary in Scientific Language

**The aim of the study is the examination of the efficacy and safety of a dietary supplement with tocotrienols and PMFs and a similar emulsified formulation in probands with hypercholesterolemia and elevated hsCRP levels compared to placebo. Moreover, differences in bioavailability and efficacy between the two verum preparations will be investigated.
The course of several serum lipid and inflammatory parameters will be monitored over the study duration of 12 weeks. Moreover, the tolerance of the dietary supplements will be monitored by documenting adverse events and measuring blood glucose levels during the observation period.**

Organizational Data

- DRKS-ID: **DRKS00000589**
- Date of Registration in DRKS: **2010/10/20**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **010/2106 , Freiburger Ethik-Kommission International**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1117-4527**

Health condition or Problem studied

- ICD10: **E78 - Disorders of lipoprotein metabolism and other lipidaemias**
- ICD10: **[---]* - [---]***

Interventions/Observational Groups

- Arm 1: **verum 1: dietary supplement with tocotrienols (4.5 mg per capsule) and polymethoxylated flavones (PMF; 40.5 mg per capsule). One capsule twice a day together with food, un-chewed.**
- Arm 2: **verum 2: dietary supplement with tocotrienols (8.3 mg per capsules) and polymethoxylated flavones (PMF; 16.3 mg per capsules). One capsule twice a day together with food, un-chewed.**
- Arm 3: **placebo. One capsule twice a day together with food, un-chewed.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Other**
- Assignment: **Parallel**
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Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

LDL-Cholesterol, fasting blood sample every examination (week -2, week 0, week 6, week 12)

Secondary Outcome

Lipid parameters (TC, TG, HDL), Inflammation parameters (hsCRP, TNF-a), Liver enzymes: AST, ALT, γGT, Blood glucose, Blood picture, Anthropometric data (height, weight, BMI)
Blood pressure and pulse, Family anamnesis. Fasting blood sample and questionnaires every examination (week -2, week 0, week 6, week 12).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/11/01**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

Caucasians, LDL-C ≥ 130 mg/dL (≥ 3.3 mmol/L) and, persisting hsCRP ≥ 2 mg/L, written confirmation of participants after detailed oral and written explanation about the study contents, and - requirements, ability and willingness of the participants to attend the investigator's orders (compliance of the study conditions, consumption of the dietary study supplements according to the dosage recommendation)

Exclusion criteria

Triglyceride ≥ 400 mg/dL (≥ 4,5 mmol/L).
Total Cholesterol ≥ 500 mg/dL (≥ 13 mmol/L).
hsCRP ≥ 10 mg/L.
Body-Mass-Index (BMI) ≥ 35.
Simultaneous treatment with lipid lowering medication (e. g. Fibrates, bile acid exchanger resin, phytosteroles, Ezetimibe).
treatment with HMG-CoA-reductase inhibitors (statins) in the last three month.
Simultaneous consumption of coagulation-inhibiting drugs (for example Marcumar)
routine consumption of laxative.
taking any supplements with omega-3 fatty acids, Vitamine E, phytosteroles, polyglucosamines (Chitosan) or other lipid binding ingredients.
heavy chronic diseases (tumors, diabetes typ 1, etc.), documented coronary heart disease, blood clotting disorders, renal failure, liver diseases.
chronic inflammatory diseases (e. g. Colitis ulcerosa, Morbus Crohn, rheumatoid arthritis).
allergy or intolerance to any ingredients of the test products.
common exclusion criterias like
opregnancy and lactation

Addresses

- **Primary Sponsor**

  Leibniz Universtiät Hannover
  Institut für Lebensmittelwissenschaft und Humanernährung
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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/07/28**

Trial Publications, Results and other documents

** 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.*