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

Trial Description

Title

Influence of specific collagen hydrolysate on muscle mass in obese men

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Based on the planned double-blind placebo-controlled clinical study, the influence of the muscle mass in obese men between 30 and 60 years of age should be examined by the administration of specific collagen peptides compared to placebo. On the basis of previous study data the combination of a strength training and the intake of protein assumed an increase in muscle mass with a concomitant improvement in muscle strength . A total of 120 men have to participate in the study. In this proposed study the division into intervention groups of 40 subjects is set. In addition to performing a traditional strength training (three-set training) the participants are taking collagen peptides or placebo. Primary endpoint is the change in muscle mass through the administration of collagen peptides compared to placebo. The body composition will be detected by DEXA. In an additional test group the influence of whey protein will be examined. Besides an improvement in arm and leg strength changes in fat mass and changes in the metabolic risk profile (waist circumference, triglycerides, total cholesterol, HDL - (/ LDL cholesterol, blood pressure, glucose, insulin, HbA1c, HOMA-IR, hs-CRP) are secondary outcomes. Additionally it is examined to what extent the effects draw a distinction between taking whey protein and collagen peptides or placebo. Participants must have an increased fat mass (> 25%) have to be clinically healthy and must be able to do an one-hour strength training three times a week by a period fully in three months. Furthermore possible participants must not regular exercise 60 minutes or more per week until the start of the study. In addition, no intolerance to the study products must be present. After a successful test of the inclusion and exclusion criteria based on a detailed medical history, clinical examination and a blood test the arm and leg strength measurement will be held . Randomly, the subjects are divided into three study groups (collagen peptides, whey protein and placebo). According to the manufacturer 15 grams of the investigational product (collagen peptides), the taste like placebos or the whey protein are ingested dissolved in water daily. At training days the product is taking immediately after the work out. On Days when training do not take place, the substance will be consumed at the same time as on training days during the 12-week study period. 2 examination dates take place:.. U1: initial examination U2: final examination after 12 weeks of training intervention objective of the planned double- blind placebo-controlled clinical

study is the influence of sarcopenia (grade I or II) in obese men between 30 and 60 years of age by oral administration of collagen peptides

Brief Summary in Scientific Language

Primary endpoint of the planned double-blind placebo-controlled clinical study is the influence of the muscle mass in obese men between 30 and 60 years of age by oral administration of specific collagen peptides. The body composition will be detected by DEXA. Besides improving arm and leg strength changes in fat mass and changes in the metabolic risk profile (waist circumference, triglycerides, total cholesterol, HDL - (/ LDL cholesterol, blood pressure, glucose, insulin, HbA1c, HOMA-IR, hs-CRP) will be secondary outcomes .
Additionally it is examined to which extent the effects are influenced by the oral administration of whey protein and in which extent they draw a distinction between taking whey protein and collagen peptides or placebo.
On the data basis of existing studies is to assume that the combination of strength training with the use of specific collagen peptides promotes the increase in muscle mass and may improve body composition (reduction of fat mass) and force capability. Based on a sample size calculation, the clinical study of 120 men aged 30 to 60 years (40 collagen peptides, 40 placebo, 40 whey protein) over a period of 12 weeks is carried out

Organizational Data

- DRKS-ID: **DRKS00008925**
- Date of Registration in DRKS: **2015/09/01**
- 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.: **205/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **R54 - Senility**

Interventions/Observational Groups

- Arm 1: **-U1: Entrance examination with control of the inclusion and exclusion criteria with help**
  followed by 12 weeks of strength training (3 times 60 min per week) and supplementation of 15
  grams of collagen hydrolysate (BODYBALANCE TM) per day

-U2: Final examination after 12 weeks like U1

- Arm 2: **-U1: Entrance examination with control of the inclusion and exclusion criteria with help**
  followed by 12 weeks of strength training (3 times 60 min per week) and supplementation of 15
  grams of whey protein per day

  -U2: Final examination after 12 weeks like U1

- Arm 3: **-U1: Entrance examination with control of the inclusion and exclusion criteria with help**
  followed by 12 weeks of strength training (3 times 60 min per week) and supplementation of placebo per day

  -U2: Final examination after 12 weeks like U1

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor, data analyst**
- Control: **Placebo**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Change in muscle mass after the 3-month training period and supplementation of collagen peptides compared to placebo supplementation verified by DEXA measurement

Secondary Outcome

Secondary outcomes are improving arm and leg strength, changes in fat mass and changes in the metabolic risk profile (waist circumference, triglycerides, HDL / LDL cholesterol, blood pressure) after the 3-month training period.

Additionally it is examined to which extent the effects are influenced by the oral administration of whey protein and in which extent they draw a distinction between taking whey protein and collagen peptides or placebo.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Institut für Sport und Sportwissenschaft, Freiburg im Breisgau, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/11/01**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **30 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

-decreased muscle mass (DEXA measurement) and function (Handgrip measurement)

- increased fat mass > 25% as measured by BIA

- No subjective symptoms during exercise
- Stable weight and eating behavior
- No previous regular physical activity > 60min / week

- No contraindications against physical stress correspondending guidelines of ACSM.

- No contraindications aaginst additional nutritional or ergogenic supplements

Exclusion criteria

-contraindications regarding sports activities according to the criteriae of the ACSM, 2009

-Diagnosis of cancer within the last 5 years

-Allergy/aversion against animal protein

-Inability to perform a strenght training

-Arterial hypertension (RRsyst > 200 mmHg und/oder RRdiast > 105 mmHg) under resting conditions

-Insulin dependant Diabetes mellitus type II
Liver oder kidnes disease with a non-permission to ingest higher concentraions of protein.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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URL: **www.gelita.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/09/30**

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.*