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

Trial Description

Title

Body compositional and endocrine-metabolic changes by long-term lifestyle intervention with health education, diet (Almased®), physical activity or a combination of diet and physical activity in obese persons

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Eligible overweight and obese persons will be randomized. After randomization the study consists of three controlled groups: 1 group of participants is treated by health education for life style intervention only. The other 2 groups will be included in a dietary program with an individually dosed food supplement (Almased®) for an initial weight reduction for a period of 6 weeks. The following 18 weeks represent the most important phase of weight loss and attitude, the participants take part in 2 different interventions according to their randomization. One group will continue the dietary program, one group will try to achieve and maintain weight reduction by continuing the initial dietary program together with an additional physical activity program. For all intervention groups the following 6 months aim at a further stabilization of weight and attitude, now without defined guidelines of intervention but with the intention to continue the so far practiced change in life style. All participants will be supplied with adequate information and material concerning the desired change in life style.

Brief Summary in Scientific Language

Obese and adipose participants are randomized to three intervention groups. During the first six weeks of the program, the subjects assigned to the substitutional diet group (SD-G) were instructed to replace two daily meals with a commercially available soy-joghurt-honey preparation (Almased®). During the following 18 weeks, only one daily meal was replaced by the preparation. The dietary intake of fat during this second phase was not to exceed 60g per day. The first 6-week diet contained about 1000 kcal per day for women and 1200 kcal for men, and then, in the following weeks, aimed at a maximum of 1500 kcal for women and 1700 kcal for men. In addition, a second group of subjects were encouraged to additionally attend a 60-minute physical activity endurance program twice weekly. Otherwise, they were to follow the same rules as the substitutional diet group (SD/PA-G).
The lifestyle education group (LE-G) attended, after enrolment, three teaching sessions bi-monthly and had individual consultations during weeks 6, 24 and 48.

All sessions were held by experts in nutritional counselling. Subjects received a diet-overview handout, in accordance with the ?German Society of Nutrition? and the ?German Society of Sports Medicine and Prevention?. Prescribed was a moderate-fat, nutrient-balanced reduction diet consisting of 1200 to 1500 kcal per day for women and 1500 to 1800 kcal per day for men, with approximately 60 percent of the calories coming from carbohydrates, 25 percent from fat, and 15 percent from protein.
The data collected at enrolment and after 6, 24 and 48 weeks were body weight, waist and abdominal circumference, self-reported medical history, blood pressure, glucose, insulin, serum lipids and inflammatory markers (C-reactive protein, IL-6). For measurement of body composition, the technique of air displacement plethysmography was used (Bod Pod). Dietary compliance was estimated by 24-hour recalls of dietary consumption.

Organizational Data

- DRKS-ID: **DRKS00000010**
- Date of Registration in DRKS: **2008/09/05**
- Date of Registration in Partner Registry or other Primary Registry: **2006/06/14**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **230/01 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- Primary Registry-ID: **NCT00356785 (ClinicalTrials.gov)**
- Partner Registry-ID: **UKF000723 (Register Klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- ICD10: **E66.0 - Obesity due to excess calories**
- Free text: **Diet**
- Free text: **overweight**

Interventions/Observational Groups

- Arm 1: **The substition group (SD-G) has been instructed to substitute two daily meals by the customary in commerce soja protein-joghurt-product-compound (Almased®) in individual doses during the first 6 weeks in order to limit the calorie delivery as defined.**
During the following 18 weeks it is planned to substitute only one meal per day. The fat delivery may not exceed 60g/d in the defined period. This results in a calorie intake of approximately 1000 kcal/d within the first 6 weeks for women and 1200 kcal/d for men. Within the coming 18 weeks the women's

intake may not exceed 1500 kcal/d, men's intake may not exceed 1700 kcal/d.

- Arm 2: **The second group (SD/PA-G) will participate in a physical endurance training twice a week. However, the nutrition instructions for them as for the SD-group will be the same.**
- Arm 3: **Three training dates are provided for the members of the lifestyle-group (LE-G) within the next two month and three individual training programs in week number 6, 24 and 48.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Body weight loss of 5% and 10 %

Secondary Outcome

Reduction of body fat
Change of muscle mass

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2002/02/01**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **35 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

- Eligible participants must have overweight with a BMI between 27,5 and 35 kg/m²
- The participants must be able to participate in a physical activity program
- The participants must be willing to participate in the program for 1 year
- Written informed consent must be given to accept randomization to either of the intervention groups

Exclusion criteria

- Participants who do not meet all entry criteria
- BMI > 35,0 kg / m²
- Performance capacity < 75 w for 2 min
- Subjects younger than 35 yrs (with reference age at 1st Jan 2002: 34.5 yrs) or older than 65 yrs (with reference age at 1st 2002: 65.5 yrs)
- Absolute or relative contraindications to exercise testing of the ACSM
- Persons unable or with restrictions to participate in a regular physical activity program because of any disease (e.g. history of CHD, arrhythmia, valvular heart disease, arthritis of major joints)
- Severe hypertension systolic BP of > 200 mm Hg and or diastolic BP of > 105 mm Hg at rest
- Persons with established insulin dependent diabetes mellitus (IDDM)
- Persons with a disease of the liver or the kidneys prohibiting high protein intake
- Persons with a disease of the thyroid gland or taking thyroid hormones

Addresses

- **Primary Sponsor**

  Universitätsklinikum Freiburg
  Hugstetter Str. 55
  79106 Freiburg
  Germany

Primary Sponsor

Universitätsklinikum Freiburg
Hugstetter Str. 55
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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **http://www.uniklinik-freiburg.de/ip/live/index_de.html**

■ **Contact for Scientific Queries**

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URL: **http://www.uniklinik-freiburg.de/sportmedizin/live/index.html**

■ **Contact for Public Queries**

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URL: **http://www.uniklinik-freiburg.de/medizin/live/patientenversorgung/medizin8.html**

Sources of Monetary or Material Support

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

Almased Wellness GmbH
29550 Bienenbüttel

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

Almased Wellness GmbH
29550 Bienenbüttel

Telephone: **[---]***
Fax: **[---]***
E-mail: **atrouille at almased.de**
URL: **http://www.almased.de/cms/front_content.php?idcat=28**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2002/12/01**

Trial Publications, Results and other documents

- Paper **Weight loss without losing muscle mass in pre-obese and obese subjects induced by a high-soy-protein diet.**
  Deibert P, Konig D, Schmidt-Trucksaess A, Zaenker KS, Frey I, Landmann U, Berg A.
  Int J Obes Relat Metab Disord 2004; 28(10):1349-52

** 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.*