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

### Trial Description

**Title**

Effectiveness of a multilateral weight reduction conception

**URL of the trial**

[---]*

**Brief Summary in Lay Language**

The goal of this study in terms of nutritional physiology is to examine the effects of a combined nutritional procedure (protein-rich formula diet combined with fatbinding tablets) in connection with diet and sport instructions on weight reduction and selected parameters in obese persons (BMI 28-35 kg/m²).

**Brief Summary in Scientific Language**

This study examines the effects of a combined nutritional procedure composed of a protein-rich formula diet as a meal replacement combined with lipidbinding tablets (Polyglucosamine L112) in connection with diet and sport instructions on weight reduction and selected parameters (lipid and glucose metabolism) in obese persons (BMI 28-35 kg/m²).

**Do you plan to share individual participant data with other researchers?**

[---]*

**Description IPD sharing plan**

[---]*

### Organizational Data

- **DRKS-ID:** DRKS00000325
- **Date of Registration in DRKS:** 2010/02/01
- **Date of Registration in Partner Registry or other Primary Registry:** [---]*
- **Investigator Sponsored/Initiated Trial (IST/IIT):** no
DRKS-ID: **DRKS00000325**
Date of Registration in DRKS: **2010/02/01**
Date of Registration in Partner Registry or other Primary Registry: [---]*
Investigator Sponsored/Initiated Trial (IST/IIT): **no**
Ethics Approval/Approval of the Ethics Committee: **Approved**
(leading) Ethics Committee Nr.: **09/2638**, Freiburger Ethik-Kommission International

### Secondary IDs
- Universal Trial Number (UTN): **U1111-1113-5324**
- Sponsor-ID: **003/09** (Studiennummer)

### Health condition or Problem studied
- ICD10: **E66.0 - Obesity due to excess calories**
- ICD10: [---]* - [---]*

### Interventions/Observational Groups
- Arm 1: **verum group: intake of two fatbinding tablets per day**
- Arm 2: **Placebo group: intake of two placebo tablets per day**

### 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**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*
Primary Outcome

body weight, BMI at any appointment (week 0, week 6, week 12, week 18)

Secondary Outcome

waist circumference, Bioelectrical impedance analysis, blood pressure, several blood parameters (e.g. glucose, insulin, TC, HDL, LDL, TG), questionnaire at any appointment (week 0, week 6, week 12, week 18)

Countries of recruitment

- DE Germany

Locations of Recruitment

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2009/12/01
- Target Sample Size: 120
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 30 Years
- Maximum Age: 60 Years

Additional Inclusion Criteria

- caucasian men and women at the age of 30-60 years
- Body Mass Index between 28,0 and 35,0 kg/m²
- proband’s written agreement to investigation after oral and written education about study content, demands and risks
- proband’s willingness to replace one meal by a formula diet and to consume two fatbinding tablets per day
- proband’s willingness to follow the given recommendations concerning nutrition and physical activity
Exclusion criteria

- severe chronic illness (manifest chd, cancer)
- insulin-dependent diabetes mellitus Typ I and II
- severe kidney or liver diseases
- chronic gastrointestinal diseases (especially small intestine e.g. duodenal ulcer, liver, pancreas) and state after gastrointestinal surgical procedure e.g. nontropical sprue, short bowel syndrome)
- stomach stapling operations, gastric band
- known endocrine and immunological diseases
- lactose malabsorption
- intolerance towards soy and milk protein
- continuous intake of laxatives
- continuous intake of corticosteroids (not inhalation), psychotropic drugs
- pregnancy
- lactation
- addiction to alcohol and/or drugs
- immediate planned surgery
- simultaneous participation at another clinical trial or participation within the last 30 days
- missing consent
- refusing / reset of the consent

Addresses

**Primary Sponsor**

Leibniz Universität Hannover  
Institut für Lebensmittelwissenschaft und Ökotrophologie  
Abteilung Ernährungsphysiologie und Humanernährung  
Mr. Prof. Dr. Andreas Hahn  
30167 Hannover  
Germany

Telephone: [---]*  
Fax: [---]*  
E-mail: [---]*  
URL: www.nutrition.uni-hannover.de

**Contact for Scientific Queries**

Leibniz Universität Hannover  
Institut für Lebensmittelwissenschaft und Ökotrophologie  
Abteilung Ernährungsphysiologie und Humanernährung  
Mr. Prof. Dr. Andreas Hahn  
Am Kleinen Felde 30  
30167 Hannover  
Germany

Telephone: 0049 (0)511 762 - 5093  
Fax: [---]*  
E-mail: hahn at nutrition.uni-hannover.de  
URL: www.nutrition.uni-hannover.de

**Contact for Public Queries**
Contact for Public Queries

Leibniz Universität Hannover
Institut für Lebensmittelwissenschaft und Ökotrophologie
Abteilung Ernährungsphysiologie und Humanernährung
Ms. Janina Postler
Am Kleinen Felde 30
30167 Hannover
Germany

Telephone: 0049 (0)511 762 - 5755
Fax: 0049 (0)511 762 - 5729
E-mail: postler at nutrition.uni-hannover.de
URL: www.nutrition.uni-hannover.de

Sources of Monetary or Material Support

- Commercial (pharmaceutical industry, medical engineering industry, etc.)
  - Certmedica International GmbH
    - Magnolienweg 17
    - 63741 Aschaffenburg
    - Germany
    - Telephone: [---]*
    - Fax: [---]*
    - E-mail: [---]*
    - URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2010/06/30

Trial Publications, Results and other documents

- Abstract Hahn A, Postler J (2011): Multifactorial intervention for weight loss, obesity reviews 12, Suppl. 1, S. 278
- Abstract Plötz S, Postler J, Hahn A (2011): Effectiveness of a multilateral weight reduction conception on cardiovascular risk factors, obesity reviews 12, Suppl. 1, S. 205
DRKS-ID: DRKS00000325
Date of Registration in DRKS: 2010/02/01
Date of Registration in Partner Registry or other Primary Registry: [---]*

* 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.