## Trial Description

### Title

**Influence oft prebiotics and probiotics on gut colonization, weight, lipid profile and blood sugar levels in overweight adults**

### Trial Acronym

**[---]***

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**The intestinal microbiota has several effects on the hosts health. Studies suggest that it may be related to the presence of obesity and metabolic diseases like diabetes. The study wants to examine the effect of a prebiotic-probiotic-preparation on weight, blood lipids and blood sugar levels.**
**Probiotics are living bacterias which are intended to colonize the large intestine and confer physiological health benefits to the host. Prebiotics are dietary supplements which can modulate the microbiota in a healthy way.**
**We believe that the application of one of the two study drugs leads to greater weight loss, a more pronounced reduction in blood sugar and the triglyceride and cholesterol levels than the placebo.**

### Brief Summary in Scientific Language

**Several human intervention studies have been performed that have demonstrated that consumption of certain pre- or probiotics can result in statistically significant changes in the composition of the gut microbiota. It is known, that the gut microbiota influences body weight, blood sugar levels and lipid profile.**
**In this study comparisons of the microbiota, body weight, blood sugar, levels, lipid profiles should be made among 20 obese individuals, which receive one of two synbiotics for 12 weeks to 10 obese individuals, who receive a placebo.**

**Study hypothesis: UK-Darmflora or the new preparation are superior to placebo in terms of weight reduction, lowering of blood sugar and the triglyceride and cholesterol levels**

## Organizational Data

- DRKS-ID: **DRKS00008729**
- Date of Registration in DRKS: **2015/06/29**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
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Investigator Sponsored/Initiated Trial (IST/IIT): **no**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **17615 , Coburg - Ethikkommission der Hochschule Coburg, Friedrich-Streib-Straße 2, 96450 Coburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **E66.90 - [generalization E66.9: Obesity, unspecified]**
- ICD10: **E11.90 - [generalization E11.9: Non-insulin-dependent diabetes mellitus; Without complications]**

## Interventions/Observational Groups

- Arm 1: **Placebo (identical capsules containing silica) for twelve weeks**
- Arm 2: **UK Darmflora, (PZN-00477512)**
  **Inulin, Lactobacillus acidophilus, Lactobazillus rhamnosus, Lactobazillus casei, Bifidobakterium bifidum for twelve weeks**
- Arm 3: **Preparation with inulin, pectin, resistant starch, Lactobacillus plantarum, Lactobacillus gasseri, Lactobacillus rhamnosus, Lactobacillus paracasei, Bifidobacterium lactis, Bifidobacterium breve for twelve weeks**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo, Active control**
- Purpose: **Prevention**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, investigator/therapist**

Control: **Placebo, Active control**

Purpose: **Prevention**

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

### Primary Outcome

**weight loss after 4, 8 and 12 weeks**

### Secondary Outcome

**blood sugar reduction after 4, 8 and 12 weeks**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Doctor's Practice **Eckernförde**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/01**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

-

Gender: **Both, male and female**

- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

### Additional Inclusion Criteria

**participants: pre-obese (BMI 25 - 29,9) and obese (BMI ≥ 30)**

### Exclusion criteria

**Immunosuppression, inflammatory bowel diseases, pregnancy, therapy with antibiotics**

## Addresses

- **Primary Sponsor**

**Postapotheke**
**Mr. Rudolf Keil**
**Auf dem Wiler 30**
**41517 Grevenbroich**
**Germany**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

**Hochschule Coburg**
**Ms. Prof. Dr. Michaela Axt-Gadermann**
**Friedrich-Streib-Straße 2**
**96450 Coburg**
**Germany**

Telephone: **0661-605860**
Fax: **0661-9621112**
E-mail: **michaela.axt-gadermann at hs-coburg.de**
URL: **http://www.hs-coburg.de/**

- **Contact for Public Queries**

**Hochschule Coburg**
**Ms. Prof. Dr. Michaela Axt-Gadermann**
**Friedrich-Streib-.Str. 2**
**96450 Coburg**
**Germany**

**Contact for Public Queries**

**Hochschule Coburg**
**Ms. Prof. Dr. Michaela Axt-Gadermann**
**Friedrich-Streib-.Str. 2**
**96450 Coburg**
**Germany**

Telephone: **0661-605860**
Fax: **0661-9621112**
E-mail: **michaela.axt-gadermann at hs-coburg.de**
URL: **http://www.hs-coburg.de/**

## Sources of Monetary or Material Support

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

**Post Apotheke**
**Mr. Rudolf  Keil**
**Auf dem Wiler 30**
**41517 Grevenbroich**
**Germany**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

## Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

## 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.*