

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

Trial Description

Title

Psychoneuroendocrine mechanisms of the regulation of hunger and satiety in obese and anorectic subjects

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Aim of the study is to investigate molecular and hormonal mechanisms of the regulation of hunger and satiety in human beings. Since most studies investigated the regulation of hunger and satiety in rodents there is limited information about the situation in human beings to date. Our study shall therefore give further insights referring to this. The intention of our study is to detect variations of blood plasma levels of certain messengers involved in the regulation of hunger and satiety in obese and anorectic compared with lean subjects and their correlations to psychological variables. This could contribute to new diagnostic and therapeutic approaches in obese and underweight patients in future.

Amendment:
Moreover associations of the above mentioned Parameters to body weight, body composition, physical activity, and energy expenditure will be investigated. For comparison between anorectic and healthy normal weight women regarding energy expenditure an additional study arm (20 healthy normal weight women) was employed.

Brief Summary in Scientific Language

Since most studies investigated the regulation of hunger and satiety in rodents there is still limited information (and predominantly from experimental designs) about the situation in humans to date. Therefore plasma levels of peptide hormones involved in the regulation of hunger and satiety (e.g. leptin, ghrelin, CCK, bombesin, obestatin, NPY, nesfatin-1, DPP-IV) will be measured in obese and anorectic subjects compared to lean controls as well as antidromic alterations of those peptides under clinical conditions during inpatient treatment and their association with body mass index, body composition, physical activity, and energy expenditure. Thus we expect further insights in the complex regulation of hunger and satiety. This could contribute to new diagnostic and therapeutic approaches in obese and anorectic patients in future.

Amendment:
Moreover associations of the above mentioned Parameters to body weight, body

composition, physical activity, and energy expenditure will be investigated. For comparison between anorexic and healthy normal weight women regarding energy expenditure an additional study arm (healthy normal weight women) was employed (n=20).

Organizational Data

- DRKS-ID: **DRKS00000442**
- Date of Registration in DRKS: **2010/11/29**
- 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.: **EA1/114/10 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **F50.0 - Anorexia nervosa**
- ICD10: **F50.1 - Atypical anorexia nervosa**
- ICD10: **E66 - Obesity**

Interventions/Observational Groups

- Arm 1: **Obese subjects (BMI > 30).**

Diagnostics of comorbidities.

Multimodal treatment with group psychotherapy, group music therapy, group art therapy, "Kommunikative Bewegungstherapie", behavior therapy based eating group, individual psychotherapy, diet counseling in groups and individual, physiotherapy/physical therapy, weighing twice a week, weekly bioimpedanceanalysis. Drug therapy of comorbidities.

No intervention other than regular treatment.

- Arm 2: **Anorexic subjects (BMI < 17,5).**

Diagnostics of comorbidities.

Multimodal treatment with a treatment contract in written form, group psychotherapy, group music therapy, group art therapy, "Kommunikative Bewegungstherapie", behavior therapy based eating group, individual psychotherapy, diet counseling in groups and individual, physiotherapy/physical therapy, weighing twice a week, weekly bioimpedanceanalysis. Drug therapy of comorbidities.

No intervention other than regular treatment.

- Arm 3: **Lean subjects (BMI 19-25) without relevant somatic disease. (Patients with somatoform disorders).**

Diagnostics of differential diagnoses.

Multimodal treatment with group psychotherapy, group music therapy, group art therapy, "Kommunikative Bewegungstherapie", individual psychotherapy, diet counseling in groups, physiotherapy/physical therapy, weekly weighing, weekly bioimpedanceanalysis. Drug therapy if necessary.

No intervention other than regular treatment.

- Arm 4: **Normal weight (BMI 19-25) healthy women. Measurement of Resting energy expenditure with indirect calorimetry and of physical activity and energy expenditure with a multisensor armband. No treatment. No intervention.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Complementary alterations in peptide hormone and enzyme levels (Oxytocin, CRF, Cortisol, CCK, Nesfatin, Ghrelin, Obestatin, PYY, Amylin, Leptin, NPY, CART, GOAT, DPP-IV, Insulin, TNF-alpha, Bombesin, GLP-1) during development towards weight restoration under treatment.

Secondary Outcome

Significant correlations between subjective perceptions (hunger etc.) and psychological variables (anxiety, depression etc.) on the one and peptide hormone plasma levels on the other side (used psychometric instruments: EDI-2 FEV, PSQ, PHQ-9, ICD-10-symptom-rating, COPE, GAD-7, BSF, GBB).
Moreover, significant correlations of peptide hormone plasma levels with measures of body composition, energy expenditure and physical activity.

Countries of recruitment



- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/09/08**
- Target Sample Size: **83**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. **anorexic subjects (according ICD-10) (BMI <17,5)**
2. **obese subjects (BMI >30)**
3. **normal weight control subjects (BMI 19-25) without relevant somatic disease**
4. **Healthy normal weight (BMI 19-25) women**

Exclusion criteria

1. **Carcinoma**
2. **Pregnancy during investigation**

Addresses

- **Primary Sponsor**

**Medizinische Klinik m.S. PsychosomatikCharité - Universitätsmedizin
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Mr. Prof. Dr. Matthias Rose
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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

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

Trial Publications, Results and other documents

- Paper **Stengel A*, Hofmann T*, Goebel-Stengel M, Elbelt U, Kobelt P, Klapp BF. (*contributed equally) Circulating levels of irisin in patients with anorexia nervosa and different stages of obesity - correlation with body mass index. Peptides. 2013 Jan; 39:125-30.**
- Paper **Goebel-Stengel M*, Hofmann T*, Elbelt U, Teuffel P, Ahnis A, Kobelt P, Lambrecht NW, Klapp BF, Stengel A. (*contributed equally) The ghrelin activating enzyme ghrelin-O-acyltransferase (GOAT) is present in human plasma and expressed dependent on body mass index. Peptides. 2013 May; 43:13-9.**
- Paper **Hofmann T, Stengel A, Ahnis A, Buße P, Elbelt U, Klapp BF NUCB2/Nesfatin-1 is associated with elevated scores of anxiety in female obese patients Psychoneuroendocrinology. 2013 Jun 21. doi:pii: S0306-4530(13)00190-X. 10.1016/j.psyneuen.2013.05.013.**
- Paper **Hofmann T*, Elbelt U*, Ahnis A, Kobelt P, Rose M, Stengel A (*contributed equally) Irisin levels are not affected by physical activity in patients with anorexia nervosa Front. Endocrinol., 06 January 2014 | doi: 10.3389/fendo.2013.00202**
- Paper **Stengel A, Goebel-Stengel M, Teuffel P; Hofmann T Buße P; Kobelt P; Rose M; Klapp BF Obese patients have higher circulating protein levels of dipeptidyl peptidase IV Peptides.**

* 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.