PLEASE NOTE: This trial has been registered retrospectively.

### Trial Description

**Title**

In-vivo-quantification of both serotonin-and norepinephrin-transporter availability in obese persons without co-morbid depression using positron emission tomography (PET) and selective radio-labelled markers - comparison with healthy controls and 6 months after a multimodal treatment program

**Trial Acronym**

IFB-PET

**URL of the trial**


**Brief Summary in Lay Language**

With the help of positron emission tomography (PET) this clinical trial investigates if and to what extent dysfunctions of so-called central neuro transmitters such as the "happiness hormone" serotonin and "stress hormone" norepinephrin are involved in the development of eating disorders and adiposity. The inclusion of further outcomes (genetic studies, stress test, MRI) will lead to a better understanding of over weight and obesity. In addition we investigate wether effects of a multimodal treatment programm could be measured or even predicted. The aim is to visualise obesity at an early stage in the human brain.

**Brief Summary in Scientific Language**

Aim of the study is
(i) to estimate neurobiological correlates of multimodal treatment program, i.e. the in-vivo SERT/ NET availability measured my means of PET and highly-selective radiopharmaceuticals [11C]DASB (SERT) and [11C]MRB (NET), respectively at baseline and 6 month after the start of a multimodal treatment program and
(ii) to correlate the availability with distinct clinical, neuropsychological (eating-behavioral), metabolic, neuroendocrinologic and genetic variables in obese persons (BMI>35) in comparison to normal-weighted controls (BMI <30).

### Organizational Data

- **DRKS-ID:** DRKS00003537
- **Date of Registration in DRKS:** 2012/05/30
- **Date of Registration in Partner Registry or other Primary Registry:** [---]*
- **Investigator Sponsored/Initiated Trial (IST/IIT):** yes
DRKS-ID: DRKS00003537
Date of Registration in DRKS: 2012/05/30
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.: 206-10-08032010, Ethikkommission an der Medizinischen Fakultät der Universität Leipzig

Secondary IDs

Health condition or Problem studied

- ICD10: E66 - Obesity
- Free text: eating behaviour, eating disorders

Interventions/Observational Groups

- Arm 1: obese persons BMI >35 undergoing DASB-PET before and after 6 month of participation in a multimodal treatment program including physical exercise, nutrition information and motivational therapy. In addition a MRI, blood withdrawals (laboratory data, leptin/ghrelin, genotyping) as well as neuropsychological/eating behaviour tests and HPA (hypothalamic-pituitary-adrenal axis) measures as tested with the combined dexamethasone suppression/corticotrophin-releasing hormone test (Dex/CRH) are performed.
- Arm 2: normal weighted persons BMI <30 undergoing DASB-PET at baseline and after 6 month. In addition a MRI, blood withdrawals (laboratory data, leptin/ghrelin, genotyping) as well as neuropsychological/eating behaviour tests and HPA (hypothalamic-pituitary-adrenal axis) measures as tested with the combined dexamethasone suppression/corticotrophin-releasing hormone test (Dex/CRH) are performed.
- Arm 3: obese persons BMI >35 undergoing MRB-PET before and after 6 month of participation in a multimodal treatment program including physical exercise, nutrition information and motivational therapy. In addition a MRI, blood withdrawals (laboratory data, leptin/ghrelin, genotyping) as well as neuropsychological/eating behaviour tests and HPA (hypothalamic-pituitary-adrenal axis) measures as tested with the combined dexamethasone suppression/corticotrophin-releasing hormone test (Dex/CRH) are performed.
- Arm 4: normal weighted persons BMI <30 undergoing MRB-PET at baseline and after 6 month. In addition a MRI, blood withdrawals (laboratory data, leptin/ghrelin, genotyping) as well as neuropsychological/eating behaviour tests and HPA (hypothalamic-pituitary-adrenal axis) measures as tested with the combined dexamethasone suppression/corticotrophin-releasing hormone test.
Characteristics

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

Primary Outcome

quantified central SERT /NET availability (binding-potential BP and distribution volume [ratios] DV[R]) in obese patients (BMI ≥ 35 kg/m²) before compared to after participation in a multimodal treatment program in order to compare BP/DV[R] between the two groups (obese, obese after paricipation of treatment program and normal weighted).

Secondary Outcome

Correlation coefficients with other parameters like genotype, stress reaction, age, gender. Comparison of the obese subjects before and after 6 month of participation in the treatment program with the normalweighted subjects.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center Klinik und Poliklinik für Nuklearmedizin; Klinik und Poliklinik für Endokrinologie und Nephrologie: IFB -Adipositas Ambulanz, Leipzig

Recruitment

- Planned/Actual: Actual
Planned/Actual: Actual

- (Anticipated or Actual) Date of First Enrollment: 2011/12/16
- Target Sample Size: 65
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: 65 Years

Additional Inclusion Criteria

- Age between 18 and 65
- BMI > 35 kg/m² resp. <30 kg/m²
- no psychotropic-medication and/or drugs for at least 8 weeks prior PET
- written informed consent

Exclusion criteria

- History of neurological or psychiatric diseases
- juvenile-onset diabetes (type 1) resp. insulin dependent diabetes type 2, malignant hypertension
- medical treatment or surgery for weight reduction less then 6 months ago
- Structural lesions (stroke, traumatic brain injury etc.)
- Cognitive deficits, major speech impairment, alcohol- or drug abuse (positive drug test)
- Major mental disorders, major communicative deficiencies which inhibit an informed consent
- neurosurgical interventions in the past
- Epilepsy, cerebral seizures in previous medical history (or in history of the family)
- Chronic diseases (e.g. asthma) indicating chronic medical treatment with central effect
- Pregnancy (exclusion via urine test before the experiment)
- Contraindications for MR imaging (e.g., implanted ferro-magnetic devices), claustrophobia

Addresses

- Primary Sponsor

  Universitätsklinikum Leipzig AöR
  Klinik und Poliklinik für Nuklearmedizin
  Mr. Prof. Dr. med. Swen Hesse
Primary Sponsor

Universitätsklinikum Leipzig AöR
Klinik und Poliklinik für Nuklearmedizin
Mr. Prof. Dr. med. Swen Hesse
Liebigstraße 18
04103 Leipzig
Germany

Telephone: +49 341/ 97 18081
Fax: +49 341/ 97 18069
E-mail: swen.hesse at medizin.uni-leipzig.de
URL: http://www.uniklinikum-leipzig.de

Contact for Scientific Queries

Universitätsklinikum Leipzig AöR
Klinik und Poliklinik für Nuklearmedizin
Mr. Prof. Dr. med. Swen Hesse
Liebigstraße 18
04103 Leipzig
Germany

Telephone: +49 341/ 97 18081
Fax: +49 341/ 97 18069
E-mail: swen.hesse at medizin.uni-leipzig.de
URL: http://www.uniklinikum-leipzig.de

Contact for Public Queries

Universitätsklinikum Leipzig AöR
Klinik und Poliklinik für Nuklearmedizin
Ms. Dipl. Biol. Franziska Zientek
Liebigstraße 18
04103 Leipzig
Germany

Telephone: +49 341/ 97 18048
Fax: +49 341/ 97 18069
E-mail: franziska.zientek at medizin.uni-leipzig.de
URL: http://www.uniklinikum-leipzig.de

Sources of Monetary or Material Support

- Public funding institutions financed by tax money/Government funding body
  (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

  Bundesministerium für Bildung und Forschung Dienstsitz Berlin
  Hannoversche Straße 28-30
  10115 Berlin
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Bundesministerium für Bildung und Forschung Dienstsitz Berlin
Hannoversche Straße 28-30
10115 Berlin
Germany

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: www.bmbf.de

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2015/03/02

Trial Publications, Results and other documents

- Paper Sex differences in serotonin-hypothalamic connections underpin a diminished sense of emotional well-being with increasing body weight
- Paper The central nervous norepinephrine network links a diminished sense of emotional well-being to an increased body weight

* 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.