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

http://www.adipositas-leipzig.de/forschung/forschungsprojekte/neuro-bildgebung/sertnet-pet-bei-adipositas-prof-dr-swen-hesse

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 additiion 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**

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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: <style fontName='DejaVu Sans' isBold='true'>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.</style>
- Arm 3: **obese persons BMI >35 undergoing MRB-PET before and after 6 month of participiation 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: <style fontName='DejaVu Sans' isBold='true'>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

(Dex/CRH) are performed.</style>

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 nomalweighted 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

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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.)**

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Hannoversche Straße 28-30
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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 **In-vivo serotonin-transporter (SERT) availability in obesity and eating behavior. J Nucl Med. 2013; 54 Suppl 2: 1848.**
- Paper **The effect of serum BDNF levels on central serotonin transporter availability in obese versus non-obese adults: A [11C]DASB positron emission tomography study**
- Paper **Sex differences in serotonin-hypothalamic connections underpin a diminished sense of emotional well-being with increasing body weight**
- Paper **Central serotonin transporter availability in highly obese individuals compared with non-obese controls: A [11C] DASB positron emission tomography study**
- 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.*