

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

Trial Description

Title

Addiction Transfer following Bariatric Surgery

Trial Acronym

TransAddict-BS

URL of the trial

[---]*

Brief Summary in Lay Language

The study investigates potential cross-addiction following bariatric surgery.

Brief Summary in Scientific Language

The longitudinal study investigates the relationship between bariatric surgery and cross-addiction. It aims at examining if obese patients with food addiction experience a transfer from food addiction to other nonfood-related addictive behaviors following bariatric surgery. Additional research questions address the impact of weight loss or weight course, obesity-related somatic conditions, and general psychopathology on addictive behaviors.

Hypotheses:

(1) Eating disorder and food addiction symptoms are reduced after bariatric surgery.

(2) Symptoms of alcohol use disorder, nicotin use disorder, and behavioral addictions (exercise dependence, hypersexuality, Internet addiction, pathological buying, gambling disorder) are increased following bariatric surgery.

(3) The reduction of eating disorder and food addiction symptoms is correlated with an increase in alcohol use, nicotine use, and behavioral addictions.

The study will include 200 adult patients who will be assessed prior surgery, as well as 6 and 12 months after Roux-en-Y-surgery. All patients will provide self-reported sociodemographic information and will answer standardized questionnaires. Weight and height will be objectively measured.

Organizational Data

- DRKS-ID: **DRKS00009900**
- Date of Registration in DRKS: **2016/01/19**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
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Date of Registration in DRKS: **2016/01/19**

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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

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

- (leading) Ethics Committee Nr.: **2618-2015 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

Health condition or Problem studied

- ICD10: **E66 - Obesity**
- ICD10: **F10.2 - Mental and behavioural disorders due to use of alcohol; Dependence syndrome**
- ICD10: **F17.2 - Mental and behavioural disorders due to use of tobacco; Dependence syndrome**
- ICD10: **F50 - Eating disorders**
- ICD10: **F63.0 - Pathological gambling**
- ICD10: **F63.9 - Habit and impulse disorder, unspecified**

Interventions/Observational Groups

- Arm 1: **The study includes adult patients with extreme obesity who will be assessed prior, as well as 6 and 12 months following Roux-en-Y-gastric bypass surgery using standardized questionnaires.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**



Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Single arm study**

Blinding: [---]*

Who is blinded: [---]*

Control: **Uncontrolled/Single arm**

Purpose: **Diagnostic**

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

Primary Outcome

Standardized questionnaires concerning addictive behaviors will be administered prior, as well as 6 and 12 months following bariatric surgery.

Secondary Outcome

Patient Health Questionnaire (PHQ), and Barratt Impulsiveness Scale (BIS-15) will be administered prior, as well as 6 and 12 months following bariatric surgery.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Herzogin-Elisabeth-Hospital, Braunschweig**
- University Medical Center **Medizinische Hochschule Hannover, Hannover**
- Medical Center **KRH Klinikum Nordstadt, Hannover**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/01**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

Bariatric surgery candidates (Roux-en-Y-gastric Bypass surgery)

Exclusion criteria

Insufficient German language skills, acute psychosis, intellectual retardation

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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<http://www.krh.eu/klinikum/NSK/kliniken/chirurgie/team/Seiten/default.aspx>

Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

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URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/05/30**

Trial Publications, Results and other documents

- Paper **Müller, A., Leukefeld, C., Hase, C., Gruner-Labitzke, K., Mall, J.W., Köhler, H., & de Zwaan, M. (2018). Food addiction and other addictive behaviors in bariatric surgery candidates. European Eating Disorder Review, 26, 585-596**

* 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.