

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

Trial Description

Title

The composition of the human intestinal MICROBIota in Anorexia Nervosa patients before and after weight gain compared with normal-weight participants (MICROBIAN)

Trial Acronym

MICROBIAN

URL of the trial

[---]*

Brief Summary in Lay Language

The human gut is a complex ecosystem which harbours a tremendous amount of microorganisms, belonging to the domains of bacteria, archaea and eucarya. Their distribution and abundance along the gut-sections varies considerably. The commensal microbiota contribute to maintaining health. Changes in the composition of intestinal microbiota have been associated with several diseases, e.g. type 2 diabetes and chronic inflammatory bowel disease.

Interestingly, there is also evidence for a relationship between gut microbiota and weight regulation. Microbial activity produces short chain fatty acids by fermenting dietary fiber and endogenous substrates. These fatty acids are assumed to contribute by 5 to 10 % to the human energy requirements. Gut microbiota differ in lean versus obese mice and humans. In several mouse models the gut microbiota could be also linked to different capacities for energy harvest from the diet. The role of gut microbiota in malnutrition has scarcely been investigated.

This gives cause for analysing stool samples of 60 female anorexia nervosa patients (age \geq 14 years) at the beginning (t1) and at the end (t2) of their in-patient stay at the Schön-Klinik Roseneck. The nutrition intake is surveyed by a food frequency questionnaire and 24 hour food records. The body composition is determined by bioelectrical impedance analysis. A validated questionnaire is used to inquire gastrointestinal symptoms. The results will be compared with data retrieved from a normal weight reference group, matched for gender and age.

Brief Summary in Scientific Language

The human gut is a complex ecosystem which harbours a tremendous amount of microorganisms, belonging to the domains of bacteria, archaea and eucarya. Their distribution and abundance along the gut-sections varies considerably. The commensal microbiota contribute to maintaining health. Changes in the composition of intestinal microbiota have been associated with several diseases, e.g. type 2 diabetes and chronic inflammatory bowel disease. Interestingly, there is also evidence for a relationship between gut microbiota and

weight regulation. Microbial activity produces short chain fatty acids by fermenting dietary fiber and endogenous substrates. These fatty acids are assumed to contribute by 5 to 10 % to the human energy requirements. Gut microbiota differ in lean versus obese mice and humans. In several mouse models the gut microbiota could be also linked to different capacities for energy harvest from the diet. The role of gut microbiota in malnutrition has scarcely been investigated.

This gives cause for analysing stool samples of 60 feemal anorexia nervosa patients (age >= 14 years) at the beginning (t1) and at the end (t2) of their in-patient stay at the Schön-Klinik Roseneck. The nutrition intake is surveyed by a food frequency questionnaire and 24 hour food records. The body composition is determined by bioelectrical impedance analysis. A validated questionnaire is used to inquire gastrointestinal symptoms. The results will be compared with data retrieved from a normal weight reference group, matched for gender and age.

Organizational Data

- DRKS-ID: **DRKS00005124**
- Date of Registration in DRKS: **2013/07/03**
- 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.: **429/2011B02 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

Health condition or Problem studied

- Free text: **anorexia nervosa**
- ICD10: **F50 - Eating disorders**

Interventions/Observational Groups

- Arm 1: **Feemal patients and an age above 14 with anorexia nervosa (all subtypes) with an indication for hospitalization with the purpose to gain weight collect stool samples at the beginning and at the end of their stay. Additionally, the nutrition intake is surveyed by a food frequency questionnaire and standardised 24 hour food records. The body composition is determined and a validated questionnaire is used to inquire gastrointestinal symptoms.**
- Arm 2: **The same investigations are performed once in a normal weight reference group, matched for gender and age**



Characteristics

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

Primary Outcome

Primary outcome is the change of the body mass index. Body weight is assessed upon admission and prior to discharge using a calibrated scale.

Secondary Outcome

Secondary outcomes are: 1) the change of body composition. Body composition is assessed upon admission and prior to discharge using a lipometer 2) the change of nutrition intake in kcal. Nutrition intake is assessed upon admission and prior to discharge using standardised 24 h food records.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Schönklinik Roseneck, Prien**
- University Medical Center **Universitätsklinikum Tübingen, Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/09/29**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**



Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2011/09/29**

Target Sample Size: **120**

Monocenter/Multicenter trial: **Monocenter trial**

■ National/International: **National**

Inclusion Criteria

■ Gender: **Female**

■ Minimum Age: **14 Years**

■ Maximum Age: **60 Years**

Additional Inclusion Criteria

Female patients and an age above 14 with anorexia nervosa (all subtypes) with an indication for hospitalization with the purpose to gain weight. Reference group: normal weight participants, matched for gender and age.

Exclusion criteria

Exclusion criteria are physical, linguistic or intellectual limitations which do not allow the patients to collect a stool sample or to follow the instructions. The decision is made by the responsible neuropsychologist. Controls: The decision is made by the examiner. If written informed consent is not provided by the participant and/or the legal guardian, this is also an exclusion criterion.

Addresses

■ Primary Sponsor

**Universitätsklinikum Tübingen, Innere Medizin VI, Psychosomatische Medizin
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URL: **http://www.psychosomatik-tuebingen.de/**

■ Contact for Scientific Queries

**Universitätsklinikum Tübingen, Innere Medizin VI, Psychosomatische Medizin
und Psychotherapie**

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■ **Collaborator, Other Address**

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83209 Prien am Chiemsee
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■ **Collaborator, Other Address**

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URL: **http://www.psychosomatik-tuebingen.de**

Sources of Monetary or Material Support

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

**SymbioPharm GmbH
Auf den Lüppen
35745 Herborn
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **http://symbiopharm.de**

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

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URL: **http://www.psychosomatik-tuebingen.de**

Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2013/08/03**

Trial Publications, Results and other documents

DRKS-ID: **DRKS00005124**

Date of Registration in DRKS: **2013/07/03**

Date of Registration in Partner Registry or other Primary Registry: [---]*



Deutsches Register
Klinischer Studien

German Clinical
Trials Register

* *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.*