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A study examining the importance of genetic variation for the ability of severely ill anorectic women to gain weight during three years

Submission date 18/12/2019	**Recruitment status** No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 15/01/2020	**Overall study status** Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/01/2020	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims
The serious psychiatric illness anorexia nervosa (AN) is primarily found in teenage girls and young women. The condition is related to several long-term morbidities and mortality but in the majority of cases there is a gradual recovery from the disorder. Intensive nutrition therapy has shown positive results in hospitalized AN patients. The fat mass and obesity-associated (FTO) gene has been associated with increased body weight and body mass index (BMI). The gene seems to be involved in the regulation of hunger and satiety, and is also associated with food intake. The aim of this study is to investigate the potential influence of the FTO gene on BMI and body composition in young women with severe anorexia nervosa during intensive nutrition therapy and after three years.

Who can participate?
Women aged 16-24 with anorexia nervosa

What does the study involve?
All patients are hospitalized for 12 weeks and are treated with an extra-high-energy diet, starting at median 75 kcal/kg/day and step by step declining to 48 kcal/kg/day over the 12-week period. The FTO gene is analyzed at study start and body composition parameters are assessed at the start of the study, after 12 weeks and at 3-year follow-up.

What are the possible benefits and risks of participating?
The treatment given to the participants is the treatment which is routine at the clinic at the time of the study. Participants' body composition is examined at three times, which means a small dose of radiation. Except this, there are no risks of participating. Benefits are that the participants are informed about their bone health and if decreased bone density is diagnosed they are referred to an osteoporotic unit.

Where is the study run from?
Queen Silvia Children’s Hospital (Sweden)

Who is funding the study?
The study is supported by grants from the Queen Silvia Children’s Hospital Research Foundation, ALF grants from Region Östergötland, The Capio Foundation, The Samariten Foundation, The H. K.H Princess Lovisa’s Foundation, The Sahlgrenska University Hospital and The Health & Medical Care Committee of the Regional Executive Board of Region Västra Götaland and by grants from the Swedish state under the agreement between the Swedish government and the county councils, the ALF-agreement (ALFGBG-716831, 678871 and 117661)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DNR 720-11

Study information

Scientific Title

The significance of the FTO gene on weight gain and body composition in young Swedish women with severe anorexia nervosa: a three-year follow-up study

Acronym
Anorexia FTO gene study

Study objectives
It is hypothesized that polymorphism of the FTO gene could explain the broad spectrum of individual weight gain during nutrition therapy and thereby provide a basis for individualized therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2011, Central Ethical Review Board of Gothenburg (Regionala etikprövningsnämnden i Göteborg, Box 401, 405 30 Gothenburg, Sweden; Tel: +46 (31)7866821; Email: barbro.morsing@epn.gu.se), DNR 720-11

Study design
Single-centre interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Participants were treated for 12 weeks with a high-energy diet. FTO was genotyped and body composition parameters were assessed by dual-energy X-ray absorptiometry and peripheral quantitative computed tomography at baseline, after 12 weeks and at 3-year follow-up.

Intervention Type
Supplement

Primary outcome measure

BMI and body composition parameters measured with dual-energy X-ray absorptiometry (DXA) and peripheral quantitative computed tomography (pQCT) at baseline, after 12 weeks of intensive nutrition therapy and after 3 years

Secondary outcome measures
The frequency and duration of physical activity per week evaluated with the International Physical Activity Questionnaire (IPAQ) at 3 years after nutrition therapy

Overall study start date
20/12/2011

Completion date
13/12/2018

Eligibility

Key inclusion criteria
1. Age between 16 and 24 years
2. Diagnosis of anorexia nervosa according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition

Participant type(s)
Patient

Age group
Mixed

Sex
Female

Target number of participants
25

Key exclusion criteria
1. Age under 16 years
2. Age above 25 years
3. Individuals with diabetes mellitus or inflammatory bowel disease

Date of first enrolment
01/02/2012

Date of final enrolment
16/06/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Queen Silvia Children’s Hospital
Sahlgrenska University Hospital
SU/Ostra sjukhuset
Gothenburg
Sweden
416 85

Sponsor information

Organisation
Sahlgrenska University Hospital

Sponsor details
The Queen Silvia Children's Hospital
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Sponsor type
Hospital/treatment centre

Website
https://www2.sahlgrenska.se/en/SU/In-English/

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Sahlgrenska University Hospital and The Health & Medical Care Committee of the Regional Executive Board of Region Västra Götaland and by grants from the Swedish state under the agreement between the Swedish government and the county councils, the ALF-agreement

Funder Name
Foundation ALF grants from Region Östergötland

Funder Name
The Capio Foundation

Funder Name
The Samariten Foundation

Funder Name
The H.K.H Princess Lovisa's Foundation

Funder Name
Queen Silvia Children's Hospital Research Foundation

Results and Publications

Publication and dissemination plan
Results from the study will be published in a peer-reviewed scientific magazine.

Intention to publish date
01/02/2020

Individual participant data (IPD) sharing plan
This study is based on patient data that cannot be shared publicly because of confidentiality under Swedish law.

IPD sharing plan summary
Not expected to be made available