

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	<input type="checkbox"/> Prospectively registered
Registration date 15/01/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 Caph 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

Female

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

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

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