

# Does muscle strength and abdominal wall function improve with weight loss after gastric bypass?

**Submission date**

27/01/2017

**Recruitment status**

No longer recruiting

**Registration date**

15/03/2017

**Overall study status**

Ongoing

**Last Edited**

03/03/2025

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☒ Record updated in last year

## Plain English summary of protocol

### Background and study aims

As obesity is becoming more common worldwide, more people are undergoing weight-loss surgery such as primary laparoscopic gastric bypass, where the digestive system is re-routed past most of the stomach so that less food is digested and it takes much less food to feel full. Weight-loss surgery often has good results on obesity and related diseases. Little is known, however, about what happens to muscle strength and the abdominal wall after weight-loss surgery. Previous studies have shown that thigh muscle strength is reduced after weight-loss surgery. The aim of this study is to collect information to see whether weight loss causes muscular strength problems that could have an effect on the decision to undergo surgery.

### Who can participate?

Patients undergoing primary laparoscopic gastric bypass.

### What does the study involve?

Blood samples are taken to measure connective tissue and wound healing markers before surgery and 1 month, 3 months and 6 months, plus 2 and 3 years after surgery. Tissue samples of the abdominal wall are collected during surgery and are also tested for connective tissue and wound healing markers. Muscle strength in the abdominal wall and thigh is measured once before, 6 months and 3-6 years after surgery. Physical ability and abdominal wall function are also measured using questionnaires before, 6 months and 3-6 years after surgery.

Persons included in the muscle strength and blood and tissue sample study will also be invited to attend semi-structured interviews using an interview guide, conducted in person or by means of video conferencing. An estimated 10 to 25 persons need to be interviewed to attain information strength. The interviews will take place one to three years after gastric bypass surgery. A later interview study will be held three to six years after surgery and focus on changes in abdominal wall function. The interviews will then be transcribed and analyzed with qualitative content analysis, where meaning units are identified, condensed and coded, and categories and themes are formulated in order to report a representative conclusion of the collected narratives.

What are the possible benefits and risks of participating?

The muscle measurements are generally well tolerated and can heighten awareness of physical ability after surgery. The extra blood samples required in this study can sometimes be taken together with regular blood samples before and after surgery. The small (5 mm) tissue samples are not expected to be noticed in any way by the participants as these are taken during surgery. The interview is an additional and possibly time-consuming activity for the participants. The interview is expected to take no longer than 30-45 minutes depending on the scope of what the participant wants to talk about, and if other health-related matters come up. However, they can decide on the place and time, and whether they wish to participate in person or via video conferencing, in order to support participation.

Where is the study run from?

1. Lycksele Hospital (Sweden)
2. Uppsala University Hospital (Sweden)

When is the study starting and how long is it expected to run for?

October 2015 to December 2027

Who is funding the study?

Umeå University (Sweden)

Who is the main contact?

Dr Jeff Wennerlund, Jeff.Wennerlund@umu.se

### **Study website**

<http://clister.se/doktorander/jeffwennerlund.html>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Dr Jeff Wennerlund

### **ORCID ID**

<http://orcid.org/0000-0003-0603-751X>

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### **Type(s)**

Scientific, Principal Investigator

### **Contact name**

Prof Karin Strigård

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

GUMP

## **Study information**

### **Scientific Title**

Does muscle strength and abdominal wall function improve with weight loss after gastric bypass? A clinical observational study

### **Acronym**

GUMP

### **Study objectives**

Research questions:

1. Does bariatric surgery improve abdominal wall function after weight loss?
2. Does weight loss after bariatric surgery cause problems with the abdominal wall?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 10/01/2016, Regional Ethics Review Board, Umeå (Samverkanshuset, Umeå University, Umeå, 901 87, Sweden; +46 (0)10-4750800; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: 2015/367-31

Since this approval, this regional board has been replaced by a national agency, the Swedish Ethical Review Authority

### **Study design**

Clinical observational study and semi-structured interviews with qualitative content analysis

**Primary study design**

Observational

**Secondary study design**

Case series

**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 (in Swedish only)

**Health condition(s) or problem(s) studied**

Obesity, weight loss, muscle strength

**Interventions**

Current interventions as of 13/12/2023:

Blood samples are collected to analyze matrix metalloproteinases, hyaluron och associated biomarkers before surgery, as well as 1 month, 3 months, 6 months, plus 2 and 3 years after. Abdominal wall muscle and fascia biopsies are also collected during surgery for analysis. Abdominal wall and thigh strength are measured with the use of BioDex System 3 before, 6 months, and 3-6 years after gastric bypass. Physical ability and abdominal wall function are also measured using the Ventral Hernia Pain Questionnaire (VHPQ), International Physical Ability Questionnaire (IPAQ) and Visual Analog Scale for abdominal wall function (VAS), all once before, 6 months and 3-6 years after surgery.

Two qualitative interview studies using Qualitative Content Analysis designed to capture experiences of change of bodily function after weight loss induced by gastric bypass surgery. The first study will take place one to three years postoperatively and focus on the changes in physical activity. A later interview study 3 to 6 years after surgery will focus on abdominal wall function.

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Previous interventions as of 03/03/2022:

Blood samples are collected to analyze matrix metalloproteinases before surgery, as well as 2 weeks, 1 month, 3 months, 6 months, and 2 years after. Abdominal wall muscle and fascia biopsies are collected during surgery for analysis of matrix metalloproteinases. Abdominal wall and thigh strength are measured with the use of BioDex System 3 before and 6 months after gastric bypass. Physical ability and abdominal wall function are also measured using the Ventral Hernia Pain Questionnaire (VHPQ), International Physical Ability Questionnaire (IPAQ) and Visual Analog Scale for abdominal wall function (VAS), all once before and once 6 months after surgery.

A qualitative interview study designed to capture experiences of change of bodily function after weight loss induced by gastric bypass surgery. Interviews will take place approximately one to three years postoperatively.

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Previous interventions as of 21/04/2020:

Blood samples are collected to analyze matrix metalloproteinases before surgery, as well as 2 weeks, 1 month, 3 months, 6 months, and 2 years after. Abdominal wall muscle and fascia biopsies are collected during surgery for analysis of matrix metalloproteinases. Abdominal wall and thigh strength are measured with the use of BioDex System 3 before and 6 months after gastric bypass. Physical ability and abdominal wall function are also measured using Ventral Hernia Pain Questionnaire (VHPQ), International Physical Ability Questionnaire (IPAQ) and Visual Analog Scale for abdominal wall function (VAS), all once before and once 6 months after surgery.

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## **Intervention Type**

Other

## **Primary outcome measure**

Current primary outcome measure as of 13/12/2023:

1. Matrix metalloproteinases, hyaluron and associated biomarkers measured from blood samples taken at baseline (pre-operatively) and 1 month, 3 months, 6 months, and 2 and 3 years postoperatively
  2. Abdominal wall and thigh muscle strength, measured with the BioDex System 3 at baseline (pre-operatively), 6 months and 3-6 years postoperatively
  3. Physical ability and abdominal wall function, measured using the Ventral Hernia Pain Questionnaire (VHPQ), International Physical Activity Questionnaire (IPAQ), and Visual Analog Scale (VAS) for abdominal wall function at baseline (pre-operatively), 6 months and 3-6 years postoperatively
  4. Semi-structured interviews describing the change in muscle strength, physical activity ability and abdominal wall function after gastric bypass surgery
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Previous primary outcome measure as of 03/03/2022:

1. Matrix metalloproteinases, measured from blood samples taken at baseline (pre-operatively) and 2 weeks, 1 month, 3 months, 6 months, and 2 years postoperatively
2. Abdominal wall and thigh muscle strength, measured with the BioDex System 3 at baseline

(pre-operatively) and 6 months postoperatively

3. Physical ability and abdominal wall function, measured using the Ventral Hernia Pain Questionnaire (VHPQ), International Physical Activity Questionnaire (IPAQ), and Visual Analog Scale (VAS) for abdominal wall function at baseline (pre-operatively) and 6 months postoperatively

4. Semi-structured interviews describing the change in muscle strength and physical activity ability after gastric bypass surgery

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Previous primary outcome measure as of 21/04/2020:

1. Matrix metalloproteinases, measured from blood samples taken at baseline (pre-operatively) and 2 weeks, 1 month, 3 months, 6 months, and 2 years postoperatively

2. Abdominal wall and thigh muscle strength, measured with the BioDex System 3 at baseline (pre-operatively) and 6 months post-operatively

3. Physical ability and abdominal wall function, measured using the Ventral Hernia Pain Questionnaire (VHPQ), International Physical Activity Questionnaire (IPAQ), and Visual Analog Scale (VAS) for abdominal wall function at baseline (pre-operatively) and 6 months postoperatively

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Previous primary outcome measure:

1. Matrix metalloproteinases, measured from blood samples taken at baseline (pre-operatively) and 2 weeks, 1 month, 3 months and 6 months postoperatively

2. Abdominal wall and thigh muscle strength, measured with the BioDex System 3 at baseline (pre-operatively) and 6 months post-operatively

3. Physical ability and abdominal wall function, measured using the Ventral Hernia Pain Questionnaire (VHPQ), International Physical Activity Questionnaire (IPAQ), and Visual Analog Scale (VAS) for abdominal wall function at baseline (pre-operatively) and 6 months postoperatively

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

30/10/2015

### **Completion date**

31/12/2027

## **Eligibility**

### **Key inclusion criteria**

1. Patients eligible for primary laparoscopic gastric bypass

2. All patients undergoing primary laparoscopic gastric bypass at Lycksele Hospital are eligible for recruitment

3. Patients undergoing surgery in Uppsala are eligible for collection of blood and tissue samples only

4. All ages

**Participant type(s)**

Patient

**Age group**

All

**Sex**

Both

**Target number of participants**

50 in group with blood and tissue samples plus BioDex measurement and questionnaires.

Another 50 with only blood and tissue samples

**Total final enrolment**

99

**Key exclusion criteria**

If, after inclusion, no or different surgery is planned

**Date of first enrolment**

30/09/2016

**Date of final enrolment**

30/09/2022

## **Locations**

**Countries of recruitment**

Sweden

**Study participating centre**

**South Lapland Surgical Center, Region Västerbotten**

Hedlundavägen

Lycksele Hospital

Lycksele

Sweden

92182

**Study participating centre**

**Uppsala University Hospital**

Department of Surgery

Uppsala  
Sweden  
75185

## Sponsor information

### Organisation

County Council of Västerbotten (Västerbottens läns landsting)

### Sponsor details

Köksvägen 11  
Umeå  
Sweden  
90185  
+46 (0)90 7850000  
landstinget@vll.se

### Sponsor type

Government

### Website

[www.vll.se](http://www.vll.se)

### ROR

<https://ror.org/04xvhsp09>

## Funder(s)

### Funder type

University/education

### Funder Name

Umeå Universitet

### Alternative Name(s)

Umeå University, Umeje universitiähta, Universitas Umenis

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### Location



## Results and Publications

### Publication and dissemination plan

Current publication and dissemination plan as of 13/12/2023:

Publication is planned in peer-reviewed journals. A total of six publications are planned:

1. The change in matrix metalloproteinases (MMPs), hyaluron and associated biomarkers before and after gastric bypass
2. Analysis of tissue samples regarding metalloproteinases (MMPs), hyaluron and associated biomarkers in conjunction with gastric bypass surgery
3. The change in abdominal muscle and thigh muscle strength as related to the questionnaires 6 months after surgery
4. The change in abdominal muscle and thigh muscle strength as related to the questionnaires 3-6 years after surgery
5. Descriptive experiences of the change in muscle strength and physical activity 1-3 years after gastric bypass surgery
6. Descriptive experiences in abdominal wall function 3-6 years after gastric bypass surgery

Studies 1, 2, 3 and 5 are expected to be published in 2024. Studies 4 and 6 are expected to be published in 2027-2028

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Previous publication and dissemination plan as of 03/03/2022:

Publication is planned in peer-reviewed journals. A total of four publications are planned:

1. The change in matrix metalloproteinases (MMPs) before and after gastric bypass
2. The change in abdominal muscle strength as related to the questionnaires and change in MMPs in both blood and tissue, as well as degree of weight loss
3. The change in thigh muscle strength in relation to the questionnaires and change in MMPs and body weight
4. Descriptive experiences of the change in muscle strength and physical activity after gastric bypass surgery.

The qualitative interview study is expected to be published in 2023, and the other three original studies in 2024-25.

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Previous publication and dissemination plan:

This study is expected to give rise to three publications:

1. The change in matrix metalloproteinases (MMPs) before and after gastric bypass
2. The change in abdominal muscle strength as related to the questionnaires and change in MMPs in both blood and tissue, as well as degree of weight loss
3. The change in thigh muscle strength in relation to the questionnaires and change in MMPs and body weight

The results are to be presented at national and international conferences. Publication is planned in peer-reviewed journals from the latter half of 2019 until at least a year later, depending on the trial end date.

**Intention to publish date**

01/01/2028

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jeff Wennerlund (Jeff.Wennerlund@umu.se).

**IPD sharing plan summary**

Available on request