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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
11/09/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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 och 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. Endoanal ultrasound is performed before surgery and 6 months after, with related questionnaires. 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 endoanal ultrasound examination is intrusive but takes no longer than approximately 2 minutes.
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

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Type(s)
Scientific, Principal Investigator

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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), 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 11/09/2025:

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. Endoanal ultrasound is performed before and 6 months after surgery, together with Wexner Score and Low Anterior Resection Syndrome Score (LARS).

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 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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Blood samples are collected to analyze matrix metalloproteinases before surgery, as well as 2 weeks, 1 month, 3 months and 6 months 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.

Intervention Type
Other

Primary outcome measure

Current primary outcome measure as of 11/09/2025:

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
5. Change in external (EAS) and internal anal sphincter (IAS) measured with endoanal ultrasound before and 6 months postoperatively, with incontinence and urgency measured with Wexner Score and Low Anterior Resection Syndrome (LARS).

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Previous 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

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90185
+46 (0)90 7850000
landstinget@vll.se

Sponsor type
Government

Website
www.vll.se

ROR
https://ror.org/04xvhsp09

Funder(s)

Funder type
University/education

Funder Name
Umeå Universitet

Alternative Name(s)
Umeå University, Ubmeje universitiähta, Universitas Umensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 11/09/2025:
Publication is planned in peer-reviewed journals. A total of seven 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
7. The change in muscle thickness of the anal canal and how it relates to urgency and incontinence 6 months after surgery

Studies 1, 3, 5 and 7 are expected to be published in 2025. Study 2 is expected to be published in 2026. Studies 4 and 6 are expected to be published in 2027-2028.

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

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 the published in 2023, and the other three original studies in 2024-25.

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