

Different Limb Lengths in Gastric Bypass Surgery: Study Protocol for A Swiss Multicenter Randomized Controlled Trial (SLIM)

Marko Kraljević

University Hospital Basel <https://orcid.org/0000-0001-5243-6269>

Romano Schneider

Clarunis University Center for Gastrointestinal and Liver Diseases

Bettina Wölnerhanssen

St. Clara Reserach

Marco Bueter

UniversitätsSpital Zurich

Tarik Delko

Clarunis University Center for Gastrointestinal and Liver Diseases

Ralph Peterli (✉ ralph.peterli@clarunis.ch)

Clarunis University Center for Gastrointestinal and Liver Diseases

Study protocol

Keywords: Randomized controlled trial, Roux-en-Y gastric bypass, different limb lengths, weight loss.

Posted Date: October 20th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-31539/v1>

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Version of Record: A version of this preprint was published at Trials on May 19th, 2021. See the published version at <https://doi.org/10.1186/s13063-021-05313-6>.

Abstract

Background Obesity and type 2 diabetes mellitus (T2DM) are reaching epidemic proportions. In morbidly obese patients, bariatric operations lead to sustained weight loss and relief of comorbidities in the majority of patients. Laparoscopic Roux-Y-gastric bypass (RYGB) is one of the most frequently performed operations, but it is still unknown why some patients respond better than others. Therefore, a number of variations of this operation have been introduced. Recent evidence suggests that a longer bypassed biliopancreatic limb (BPL) has the potential to be more effective compared to the standard RYGB with a shorter BPL length. This article describes the design and protocol of a randomized controlled trial comparing the outcome of a RYGB operation with a long versus short BPL.

Methods/Design The trial is designed as a multicenter, randomized, patient and observer blinded trial. The relevant ethics committee has approved the trial protocol. To demonstrate that long BPL RYGB is superior compared to short BPL RYGB in terms of weight loss and resolution of T2DM the study is conducted as a superiority trial. Postoperative percent excess body mass index loss (%EBMIL) is the primary endpoint, whereas morbidity, mortality, remission of obesity related comorbidities and quality of life are secondary endpoints. Eight hundred patients, between 18 and 65 years and with a body mass index (BMI) from 35 to 60 kg/m² who meet the regulatory rules for bariatric surgery in Switzerland will be randomized. The endpoints and baseline measurements will be assessed pre-, intra- and postoperatively.

Discussion With its high number of patients and a 5-year follow-up this study will answer questions about effectiveness and safety of long BPL RYGB and provide level I evidence for improvement of the standard RYGB. These findings might therefore potentially influence global bariatric surgery guidelines.

Trial registration This trial was registered on ClinicalTrials.gov under the identifier NCT04219787, on January 7th, 2020.

Background

The rising prevalence of morbid obesity is causing a major health burden in terms of morbidity and mortality [1]. Complications of obesity, especially type 2 diabetes mellitus (T2DM), are placing growing demand on health-care resources. The prevalence of T2DM increases parallel to obesity and currently, there are 55.2 million people with T2DM in Europe, accounting for 8.5% of the adult population [2]. About half of the obesity associated health care costs in Switzerland are attributed to diabetes [3]. Morbid obesity is a chronic disease for which multimodal therapeutic management strategies are necessary, comparable to cancer treatment, to reach partial or full remission with a persistent risk of relapse and thus, long lasting follow-up is mandatory. Medical therapeutic strategies (diet, behavioral changes, or drugs) to achieve and maintain clinically significant weight loss remain limited [4].

Bariatric surgery is currently the most effective treatment for morbid obesity [4–7]. Laparoscopic Roux-en-Y gastric bypass (RYGB) is most frequently performed bariatric procedure in Switzerland [8]. From a

scientific point of view it is no longer a question if this procedure has a significant effect on metabolic control, but rather how the outcomes after RYGB can be further improved.

Since its introduction in 1967 by Mason [9] there have been many multiple technical variations of the RYGB to increase weight loss. Most studies used an alimentary limb (AL) length of 100 to 150 cm and a biliopancreatic limb (BPL) length of 50 to 120 cm, while the common limb (CL) length remained not measured [10, 11].

Scopinaro et al. [12] developed the biliopancreatic diversion (BPD) technique in 1979 and concluded that the BPD seems to be the most powerful treatment for hyperlipidemia and T2DM. Available evidence suggests that the extended BPL length in patients after BPD may be one of the key factors explaining the superiority of this procedure, which is further supported by some observational studies reporting greater weight loss in patients after RYGB with a longer BPL [14–16].

To this day, only one randomized controlled trial (RCT) [17] compared long BPL RYGB (150 cm BPL, AL 75 cm) with a short BPL RYGB (BPL 75 cm, AL 150 cm) in 128 patients and found a significant increase in percent excess weight loss (%EWL) for patients with long BPL RYGB in the first four years after surgery. However, the underlying mechanism of a greater weight loss after long BPL RYGB remains unclear. Furthermore, lengthening of the BPL cannot be done limitless as it carries an increasing risk of severe malnutrition. Neither of the two procedures seems to be technically more challenging, since the complication rates didn't show any significant difference [17]. However, a limitation of this study was the cohort of 146, which was too small to show any advantage in terms of comorbidities resolution or quality of life changes.

Therefore, our aim is to investigate if a longer BPL in RYGB leads to greater weight loss and superior remission of comorbidities in morbidly obese patients without reducing its safety. No matter which outcome will be obtained, our results will provide level I evidence for an improvement of the standard laparoscopic RYGB and thus may potentially influence global bariatric surgery guidelines.

Methods/design

The overall objective of this study is to evaluate whether long BPL RYGB is superior compared to short BPL RYGB in treating morbid obesity and the associated comorbidities.

Primary objective

The primary objective of this study is to investigate the %EBMIL 5 years after long BPL short BPL RYGB.

Secondary objective

The secondary objectives are to assess the percent total weight loss (%TWL), remission of comorbidities, complication rate/safety and quality of life 5 years after long and short BPL RYGB.

Study design and site

This is a multicenter, randomized, controlled, patient and observer blinded, superiority trial in morbidly obese patients receiving either long BPL or short BPL RYGB. The trial has been registered on ClinicalTrials.gov under the identifier NCT04219787. This protocol has been written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (additional file 1). The planned visit and examination schedule is presented in Fig. 1.

Sample size

A total of 800 morbidly obese patients scheduled for RYGB will be randomly assigned to the two types of surgery with 400 patients assigned to each treatment arm. A loss of follow-up at one year of 2.5% is considered realistic and it has been accounted for a drop-out of 10%.

Inclusion criteria

Participants fulfilling the following criteria are eligible for the study:

- informed consent (IC) as documented by signature (Appendix Informed Consent Form)
- patients with BMI of 35 kg/m² or higher who comply with the regulatory rules for bariatric surgery in Switzerland (Swiss Society for the Study of Morbid Obesity and Metabolic Disorders [SMOB] guidelines [18])

Exclusion criteria

The presence of any one of the following exclusion criteria will lead to exclusion of the participant:

- age < 18 years or > 65 years
- BMI > 60 kg/m²
- height < 145 cm
- CL length of < 180 cm as measured intraoperatively
- ASA physical status classification > III
- previous bariatric operation
- inflammatory bowel disease
- ongoing malignant disease
- known or suspected non-compliance, drug or alcohol abuse
- psychiatric disorder

Randomization and intervention

Eligible patients, who give written confirmed consent, will be registered in the electronic data capture and management system secuTrial®, which is programmed by the Clinical Trial Unit (CTU) of the University of Basel. The database is web-based and allows online randomization stratified by the involved centers.

Enrolled patients will be randomly assigned in a 1:1 ratio to receive a long BPL RYGB (arm A) versus a short BPL RYGB (arm B). Figure 2 provides a schematic view of both types of RYGBs.

Interventions

All patients will receive standard preoperative assessment including endocrine, pulmonary function and cardiovascular assessment, psychiatric assessment, gastroscopy with Helicobacter pylori testing and abdominal ultrasound to check for liver size and gallstones. Patients in arm A will receive a RYGB with a 180 cm long BPL and an AL of 80 cm, the group B will receive a RYGB with an 80 cm BPL and a 180 cm AL. The individual technique in terms of trocar position, materials used (i.e. staplers, trocar, suture etc.) will be left to the choice of each individual surgeon. Total small bowel length will be measured during surgery; patients with a total small bowel length of less than 440 cm will be excluded from the study. Patient and observer blinded pre- and postoperative follow-up will be performed.

Study visits

Physicians blinded to the intervention will perform study documentation and patient assessment. Since the trial is designed as an observer and patient blinded RCT, information about the surgical procedure will not be disclosed during the follow-up examinations to any assessors. There will be 11 study visits in total. The study design flow diagram is presented in Table 1. Potential study participants will be identified by the preoperative outpatient clinic consultations. The first visit will be preoperative after informed consent is obtained. Then patients will receive their study intervention according to the preoperative randomization. Postoperatively, study visits will be performed at discharge, 3, 6, 9, 12 and 18 months and 2, 3, 4 and 5 years. Each study visit includes data collection of weight, blood tests, and complications. In addition, questionnaires will be also assessed to study the quality of life (Bariatric Analysis and Reporting Outcome System [BAROS] and the Gastrointestinal Quality of Life Index [GIQLI]).

Table 1

| Study Periods | Screening | Intervention | Follow-up | | | | | | | | |
|--|-----------|--------------|-----------|-----|-----|-----|-------|-----|-----|-----|-----|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Visit | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| Time (day, month, year) | - 3 m | 0-5 d | 3 m | 6 m | 9 m | 1 y | 1.5 y | 2 y | 3 y | 4 y | 5 y |
| Patient Information and Informed Consent | x | | | | | | | | | | |
| Demographics | x | | | | | | | | | | |
| Medical History | x | | | | | | | | | | |
| In-/Exclusion Criteria | x | x | | | | | | | | | |
| Physical Examination | x | x | x | x | | x | x | x | x | x | x |
| Vital Signs | x | x | x | x | | x | x | x | x | x | x |
| Laboratory Tests | x | x | x | x | | x | x | x | x | x | x |
| Randomization | | x | | | | | | | | | |
| Operation | | x | | | | | | | | | |
| Complications | | x | x | x | | x | x | x | x | x | x |
| Primary Variables | x | x | x | x | | x | x | x | x | x | x |
| Secondary Variables | x | x | x | x | | x | x | x | x | x | x |
| Adverse Events | | x | x | x | | x | x | x | x | x | x |
| Schedule of study assessments. | | | | | | | | | | | |

Study endpoints

Primary endpoint

The primary endpoint is the percent %EBMIL at one to five years postoperatively. For the %EBMIL the presurgical BMI (at hospital entry time of the patient) and postsurgical BMI at the corresponding visit will be measured.

Secondary endpoints

- %TWL
- remission of comorbidities

- complication rate
- quality of life

All comorbidities will be assessed at each visit by a physician based on symptoms, laboratory findings and use of medication. The postoperative course of comorbidities will be defined as follows: remission: no symptoms/without any medication (dyslipidemia true remission = no medication and normal lipid values); remission of T2DM will be defined according to the ADA criteria: complete remission: HbA1c < 6.0%, fasting glucose < 100 mg/dl and at least one year no active pharmacologic therapy; partial remission HbA1c < 6.5% [19]. improvement: less symptoms and/or less medical treatment/medication; unchanged: same symptoms and equivalent therapy; worsened: more symptoms or increase of therapy. De-novo comorbidity: comorbidity not present at baseline, but newly developed within 5 years postoperatively. All surgical and non-surgical complications will be assessed according to the Clavien-Dindo Classification (CDC) [20] and the Comprehensive Complication Index (CCI) [21]. BAROS [22] and GIQLI [23] scores will be used to measure postoperative quality of life.

Blinding

With exception of the team in the operating theatre, all involved medical and non-medical practitioners are blinded as well as the patient. The procedure will be named as *laparoscopic Roux-en-Y gastric bypass* in all medical records without mentioning the limb lengths. Unblinding is permitted at the end of the study and in case of surgical or medical complications, emergency consultation or other ethical considerations.

Study management and administration

Data management and monitoring is supported by the CTU of the University of Basel. Source data of every study participant are entered into the study data management system secuTrial® (interActive Systems GmbH, Berlin, Germany).

Quality control measures

Continuous central and on-site monitoring of the study is performed by the CTU for quality control and assurance purposes to evaluate the progress of the study and to verify the accuracy and completeness of eCRFs. Furthermore, the CTU will ensure that all protocol requirements are met, all applicable local authority regulations and investigator's obligations are being fulfilled and to resolve any inconsistency in the study records. Monitoring will consist of one initiation visit, one monitoring visit per year and a close-out visit per center as a minimum.

Statistical analyses

Sample size

In order to detect a difference of 10% EBMI, 2 × 98 patients would be needed for 80% power. For a 5% difference in %TWL even less. For an 18% difference in complete and partial remission rate in T2DM 2 × 102 patients with T2DM are needed. 28% of the study population suffer from T2DM, thus a total of 2 ×

364 patients for 80% power will be needed. Including a dropout rate of 5% at 5 years a total of 800 patients (400 patients for each group) should be sufficient. For a difference in the prevalence of severe adverse events of 10% 2×293 patients and for a difference of 5 CCI points 2×251 would be sufficient. For further details on calculations see section *Analysis of endpoints* below.

Analysis of endpoints

The study results will be reported in adherence to the extension of the CONSORT statement from 2010 on reporting of randomized trials [24]. Summary statistics will be used to describe and compare patient characteristics of all suitable, but non-included patients and all included patients (overall and stratified for the two treatment arms). Study endpoints will be analyzed for the intention-to-treat (ITT) population and the per protocol (PP) population. Sensitivity analysis will be conducted for the ITT population. Thereby the ITT population includes all randomized patients in the groups to which they were randomly assigned, regardless of their adherence with the entry criteria, regardless of the treatment they actually received, and regardless of subsequent withdrawal or deviation from the protocol. In the PP population all protocol violators, including anyone who switched groups or missed measurements are excluded. For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups will be given. Additional sensitivity analysis will be used if, despite all efforts taken to ensure complete data collection, the number of missing data is non-negligible or could potentially bias the results and conclusions.

Analysis of primary endpoint

The primary endpoint is the %EBMIL at postoperative year 1, 3 and 5. To examine superiority of the experimental compared to standard treatment, we will assess if the mean %EBMIL in the experimental treatment group will be significantly higher at 0.05 ($p < 0.05$) compared to the %EBMIL in the standard treatment group.

Analysis of secondary endpoints

To investigate superiority of the experimental treatment in the long-term, analysis used for the primary endpoint will be repeated for %TWL at 1, 3 and 5 years postoperatively. The number of peri- and post-surgical complications will be analyzed by the Chi-squared or Fisher's exact test dependent on the CCI score. The other secondary endpoints will be investigated using appropriate explorative methods and graphical visualization.

Ethical considerations

Participation in this trial is strictly voluntary and patients are allowed to exit the trial at any point without explanation. All eligible patients are provided an information brochure describing the study with sufficient information for them to make an informed decision about their participation in this study.

The study protocol, patients' information sheets and informed consents were approved by the local ethic committee (Ethikkommission Nordwest- und Zentralschweiz, EKNZ 2019–02392). In addition, insurance

coverage for general liability has been obtained.

Patients who decline to participate in this study are treated according to clinical standards. These patients will not be included and no study-specific follow-up will be performed.

Participants' confidentiality

The participants' confidentiality is maintained at all times. For confidentiality reasons, electronic case report forms (eCRF) do not contain any personal data of study participants. Members of the ethics committees are obliged to respect confidentiality and to refrain from divulging the participants' identity or any other personal information they might be aware of. Source data in the hospital's electronic patient information systems are secured by personal passwords and handled with respect to medical secrecy.

Archiving and data retention

The investigator will maintain all study-related records, such as eCRFs, medical records, laboratory reports, informed consent documents, safety reports, information regarding participants who discontinued, and other pertinent data. All records will be retained by the investigator as long as required by the applicable laws and regulatory requirements (10 years). Thereafter, all data will be destroyed. The study is conducted in compliance with this protocol and according to Good Clinical Practice standards as well as legal regulations. Direct access to source documents will be permitted for purposes of monitoring, audits and inspections.

Discussion

The positive effects of bariatric surgery on weight loss, obesity-related comorbidities and mortality have been widely demonstrated in long-term cohort trials and short-term RCTs [25, 26]. Over time, these procedures have improved in respect to safety and can be offered at a low mortality and morbidity [27]. The sleeve gastrectomy and the RYGB are the most common surgical procedures [28]. However, the laparoscopic RYGB is still the most commonly performed bariatric procedure in Switzerland [18]. It is no longer a question, if the RYGB has a significant effect on weight loss and on obesity-associated comorbidities, but rather how to improve the procedure and its outcomes.

The RYGB is a complex anatomical concept with various parts for potential improvement including the limb lengths. For many years, the length of the AL was thought to be the most influential factor regarding postoperative weight loss. Therefore, previous studies focused on the effects of various AL lengths, until Choban et al. showed that lengthening the AL has no effect on weight loss [29]. In contrast, the effect of the BPL length on weight loss has been studied to a much lesser extent. While the non-randomized study by Leifsson et al. reported excellent weight loss in patients with long BPL [13], only one RCT addressed this question after RYGB so far [17]. Here, the authors compared long BPL RYGB (150 cm BPL, AL 75 cm) with a short BPL RYGB (BPL 75 cm, AL 150 cm) in 128 patients and found a significant increase in %EWL for patients with long BPL RYGB 4 years after surgery. However, lengthening the BPL is not unlimited due to the increased risk of malnutrition [30]. Several studies suggest a minimal total alimentary limb length

of 300 cm, which is defined as added value of the AL and the CL, to reduce the risk of malnutrition with deficiencies of micro- and macronutrients [31–33].

Against this theoretical framework, it is difficult to draw conclusions on the optimal length of the AL and BPL, respectively, necessary to achieve the best possible outcome with a low risk of protein malnutrition. The most effective BPL length for the RYGB procedure has not been found yet since weight loss and improvement of comorbidities have only been evaluated in one non-randomized study [13] and one RCT [17].

As total bowel length varies by many meters between individuals, measuring the total length and therefore knowing the dimensions of all segments involved in RYGB will lead to a better understanding of the role of each segment in the beneficial effects after RYGB. This study investigates the effectiveness of long BPL RYGB compared to short BPL RYGB, analyzing defined clinical endpoints such as weight loss, morbidity and mortality, improvement in obesity-related comorbidities and quality of life. Furthermore, the RCT by Homan et al. [17] failed to show any significant differences in T2DM remissions as it was only powered for weight loss. Our study has enough power to address the postoperative course in terms of resolution of comorbidities.

In conclusion, the “perfect” RYGB leads to adequate %EBMIL and improvement in obesity-related comorbidities without increasing the complication rate. The SLIM trial will answer questions about effectiveness and safety after long BPL RYGB and provide level I evidence for improvement of the standard RYGB. These findings might therefore potentially influence bariatric surgery guidelines on a global level.

Trial Status

Protocol version number 1.1, 12 February 2020. The trial has received ethics approval by January 2020. The first patient will be randomized in June 2020. We expect to enroll the calculated sample size in a two to three-year time period. Estimated end of the study is December 2027.

List Of Abbreviations

AL - alimentary limb

BAROS - bariatric analysis and reporting system

BMI - body mass index

BPD - biliopancreatic diversion

BPL - biliopancreatic limb

CCI - comprehensive complication index

CDC - Clavien-Dindo classification

CL - common limb

EBMIL - excess body mass index loss

eCRF - electronic case report form

EWL - excess weight loss

GIQLI - gastrointestinal quality of life index

RYGB - Roux-en-Y gastric bypass

TALL - total alimentary limb length

TWL - total weight loss

Declarations

Ethical approval and consent to participate

The study protocol, patients' information sheets and informed consents were approved by the local ethic committee (Ethikkommission Nordwest- und Zentralschweiz, EKNZ 2019-02392). The study was also registered with the ClinicalTrials.gov registry (Registration No. NCT04219787). Written informed consent will be obtained and documented for all study participants.

Consent for publication

Not applicable.

Availability of data and material

All data will be available for other research groups interested in conducting systematic reviews. Requests for data should be directed to the Sponsor Investigator, Ralph Peterli, ralph.peterli@clarunis.ch.

Competing interests

The authors declare that they have no competing interests.

Funding

Funding was requested from the Swiss National Science Foundation, decision is pending. Otherwise no external funding was received for the trial. There are no commercial sponsors.

Authors' contributions

MK participated in the conception and design of the study and is responsible for the coordination of the study. He is the study coordinator and member of the steering committee. He drafted and revised this manuscript critically for important intellectual content and given final approval of this final version. He agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

RS drafted and has revised this manuscript critically for important intellectual content and given final approval of this final version. He agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

BW has participated in the conception and design of the study. She has revised this manuscript critically for important intellectual content and given final approval of this final version. She agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

MB is part of the steering committee. He has revised this manuscript critically for important intellectual content and given final approval of this final version. He agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

TD is part of the steering committee. He has revised this manuscript critically for important intellectual content and given final approval of this final version. He agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

RP initiated, designed and conceived this study. He is the sponsor investigator and responsible for overall study coordination. He has revised this manuscript critically for important intellectual content and given final approval of this final version. He agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors read and approved the final manuscript.

Acknowledgements

The authors would like to thank all support personnel for their hard work and dedication.

Authors' information

Our team has extensive experience in bariatric surgery. We have published several observational and interventional studies. Our last Swiss multicenter randomized study comparing RYGB and sleeve gastrectomy (SM-BOSS trial) was published in high-impact journals [34–36].

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Figures

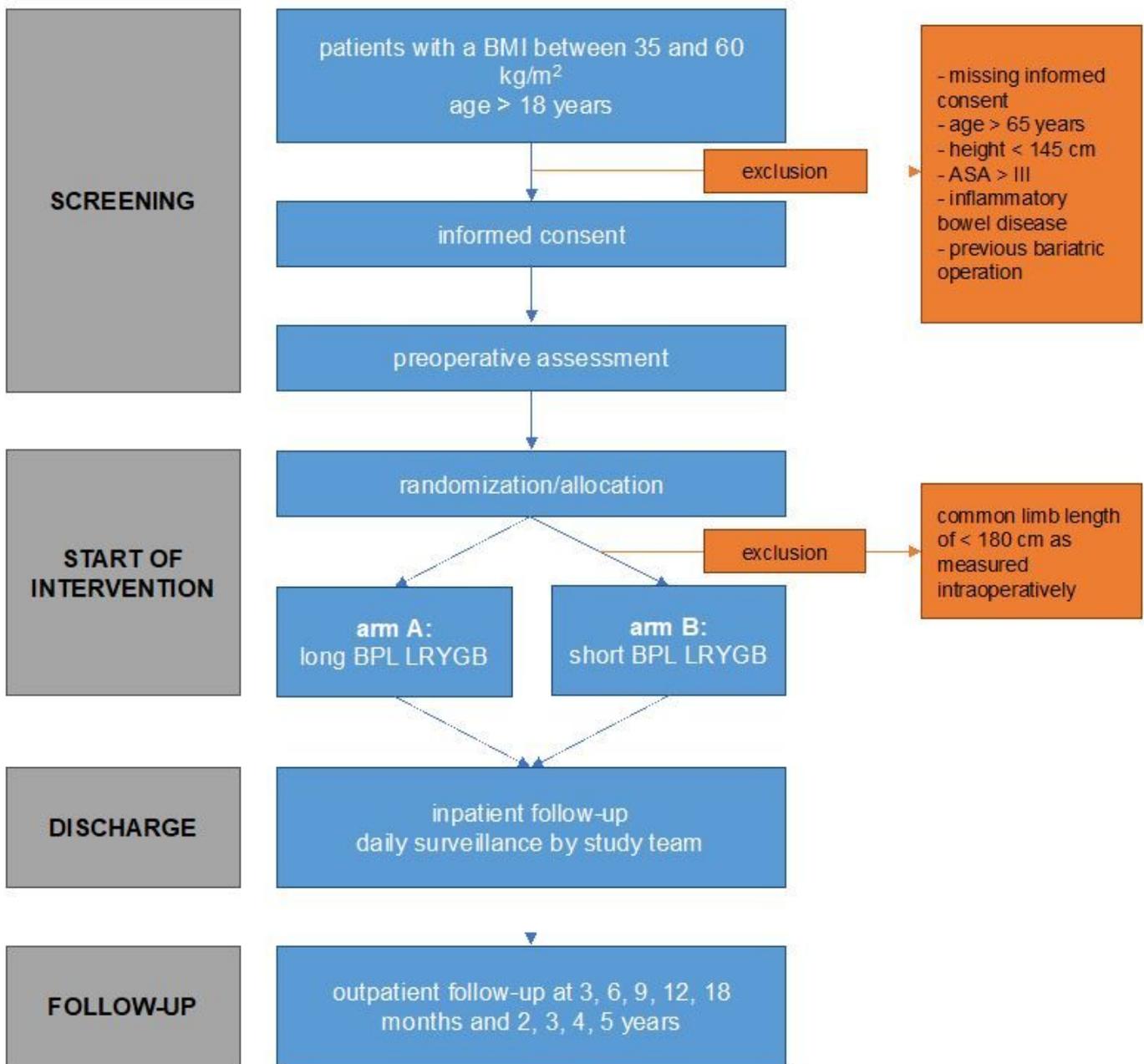


Figure 1

Schedule of enrollment, interventions, and assessments according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guideline.

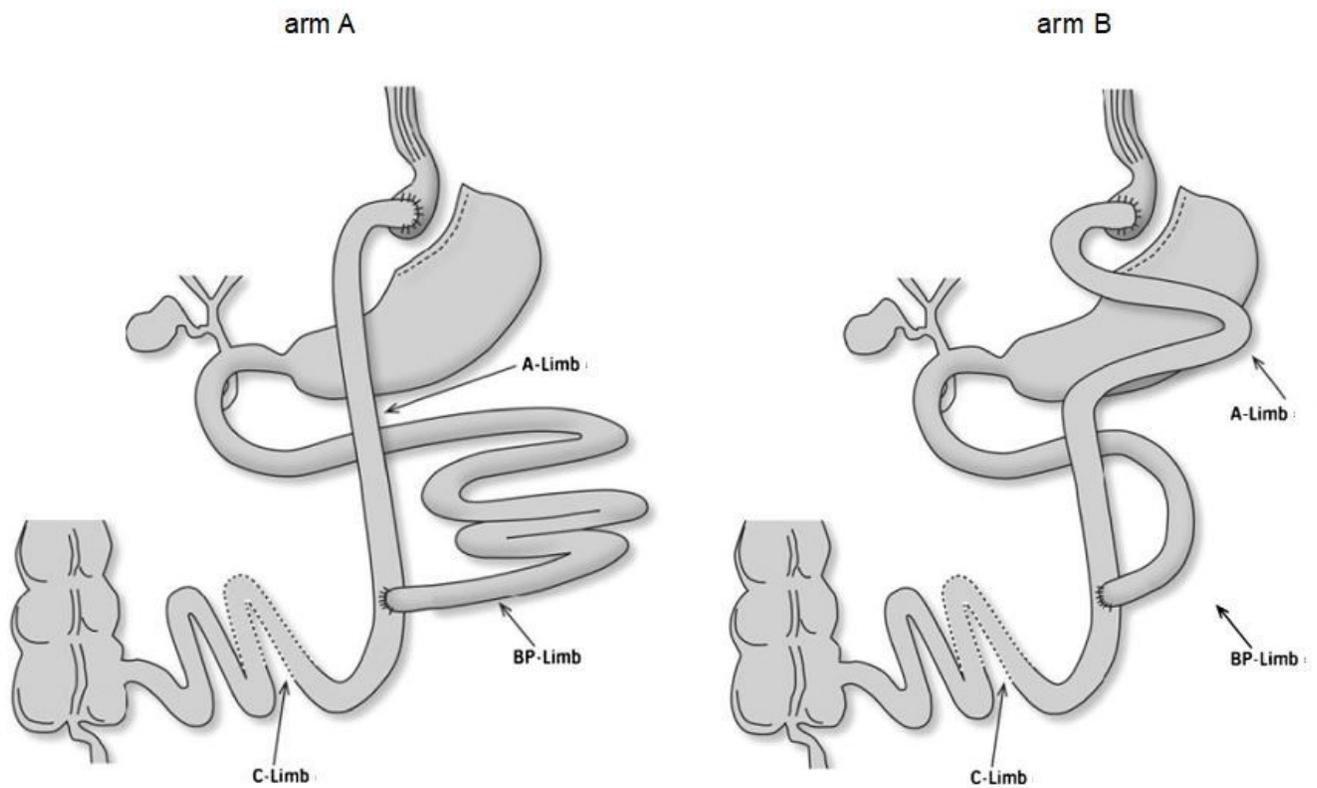


Figure 2

Enrolled patients receive a Roux-en-Y gastric bypass either with long biliopancreatic limb (BP-limb) and short alimentary limb (A-limb) or short biliopancreatic limb and long alimentary limb (A-limb). The common limb (C-limb) should remain the same for both groups.

Supplementary Files

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- [07SPIRITChecklist20200810.docx](#)