Reviewer's report

**Title:** The Sleeve Bypass Trial: a multicentre randomized controlled trial comparing the long term outcome of laparoscopic sleeve gastrectomy and gastric bypass for morbid obesity in terms of excess weight loss percentage and quality of life.

**Version:** 3  
**Date:** 29 November 2014

**Reviewer:** Ralph Peterli

**Reviewer's report:**

**General comments**

The authors describe a PRT comparing today's two most frequently performed bariatric procedures, sleeve gastrectomy (LSG) and gastric bypass (LRYGB) regarding effectiveness in terms of excessive weight loss as primary endpoint and efficacy regarding remission/improvement of co-morbidity and QoL as secondary endpoints.

**Specific comments:**

**Background:**

1. 3rd paragraph: LRYGB is considered the best surgical option... in what respect? It is the most frequently performed operation worldwide (but challenged by LSG, in 2013 almost as frequently performed, Angrisani et al, paper submitted). What does “best” mean? BPD is more potent in terms of weight loss and remission rates f.ex. T2diabetes. There exist a list of advantages of LRYGB not mentioned here: it is fully reversible, it is well documented in terms of early morbidity and long term results, often regarded as the gold standard in bariatric an/or metabolic surgery, known for more than 50 years.

2. LSG: describe how the idea of isolated LSG evolved (staged concept in pts with very high BMI (Regan, Obes Surg 2003)). Potential advantages: faster, safer (early and late i.e. no internal hernias), duodenum accessible (endoscopy), less dumping due to pylorus, second stage procedure (LRYGB or BPD-duodenal switch) are standard procedures, BUT one major disadvantage: LSG is irreversible.


**Study design:**

1. Study has started already 2 years ago (what is the purpose of publishing the design now?)
2. 3 years for 620 pts to be randomized: how well do Dutch pts accept to be randomized, Scandinavians accept much faster to be randomized for a type of surgery than other Europeans

3. with the experience of two years of recruiting is this recruitment period of 3 years still realistic?

Patient selection:
1. Exclusion criteria: GERD, 40% of morbidly obese pts suffer from GERD, give more precise definition on what criteria pts will be excluded, how to deal with hiatal hernias

Hypothesis
2. Apparently they measure not %EWL but % excessive BMI loss
3. Why QoL should be superior in LSG compared to LRYGB is based on one study, I doubt this very much

Surgical Intervention
1. How do you measure 30day morbidity in the fast track concept, when, by whom in what rhythm are the pts being followed up, give precise CRF’s of each time point or at least an overview table on follow-up appointments and what is being measured
2. Both operations described in detail
3. How many surgeons will perform the operations after what personal experience?
4. Escape surgery: you plan an intention to treat analysis, please, include also a per protocol analysis

Outcome measures:
Primary endpoint
1. Your primary endpoint is EBMIL not %EWL

Secondary endpoints:
1. How are the co-morbidities defined preop and how will remission or improvement be measured and expressed?, give more details
2. What is the follow-up setting?
3. How is the database organized?, Which CTU is responsible? How is it organized?

Power calculation
1. High number if pts for this trial, congratulate

Discussion
1. Marceau and Hess described sleeve gastrectomy as part of the BPD duodenal switch, they did not describe the LSG, this was done by Regan and Gagner as
part of a staged concept

2. LSG long term results do exist (Sieber et al, SOARD 2014 etc )

3. In case of insufficient weight loss LSG can be converted not only to LRYGB (this makes sense in pts with sever GERD after LSG or hiatal herniation of the sleeve), conversion to BPD-DS would be the standard procedure if pts are adherent to the follow-up, other option could be SADI, or mini-bypas. Please, discuss on these options

4. Do you have a definition of failure, on what basis will you diecide to go for a second stage procedure

5. How do you treat gallstones at first and in the follow up?

6. In general: it is difficult to judge with the existing protocol how well the authors will be able to measure all possible long-term complications and reoperations (vitamin deficiencies, internal hernias etc)

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests