Supplemental Online Content 2

Slaminen P, Helmiö M, Ovaska J, et al. Effect of laparoscopic sleeve gastrectomy vs laparoscopic Roux-en-Y gastric bypass on weight loss at 5 years among patients with morbid obesity: the SLEEVEPASS randomized clinical trial. *JAMA*. doi:10.1001/jama.2017.20313

SLEEVEPASS Statistical Analysis Plan

This supplemental material has been provided by the authors to give readers additional information about their work.

Laparoscopic Gastric Bypass versus Sleeve Gastrectomy to Treat Morbid Obesity (SLEEVEPASS)

Statistical Analysis Plan 19.2.2008

Saija Hurme, Biostatistician, MSc

A prospective randomized multicenter study: laparoscopic gastric bypass versus laparoscopic sleeve gastrectomy in the treatment of morbid obesity

Aim of the study

The aim of the study is to compare two different operative techniques regarding weight loss, resolution of comorbidities and complications. The primary endpoint is weight loss evaluated by %EWL (excessive weight loss, %). The secondary endpoints include resolution of associated comorbidities, improvement of QOL, mortality and morbidity of the procedures.

Hypothesis and meaning of the study

The results of this current RCT study enable comparison on the long-term data between the current golden standard of laparoscopic gastric bypass and laparsocopic sleeve gatrectomy. The hypothesis of the study is that as sleeve can be considered less traumatic and easier and faster to perform compared to RYGB, it could become the procedure of choice in treating morbid obesity provided that long-term results of SG were comparable with those of RYGB. The results can directly be applied to patient care.

Sample size calculation

Sample size calculations are based on test of mean difference of bypass and sleeve operation in excessive weight loss (EWL) in one year. The mean of 60 and standard deviation of 20 in bypass group were assumed and α-level of 0.05 were used in calculations. By using a equivalence design with a margin of equivalence of 15% (-9 to 9) a sample size of 108 patients per group is needed for 90% power. When 10% drop out is taken account, 120 patients per group were recruited for the study.

Statistical analyses

Continuous variables will be characterized by treatment and time-point using means and standard deviations (SD) or medians and range of values, and in case of categorical variables frequencies and percentages will be used.

Primary endpoint of the study is weight loss evaluated by %EWL (excessive weight loss, %) and groups will be compared using equivalence trial setting. For comparing groups the 90% confidence intervals (90% CI) for the difference between the study groups will be calculated in every time-point and the equivalence will be evaluated using the pre-defined margins of equivalence -9 to 9. When the data from the longer follow-up will be analyzed, repeated measurements ANOVA will be used and confounding factors will be taken into account in the analyses if needed.

In analyses of secondary outcomes associations between categorical variables will be tested using Pearson's χ^2 -test and in case of small frequencies Fisher's exact test will be used. Differences between groups in normally distributed continuous variables will be tested using independent samples t-test and in case of non-normally distributed variables Mann-Whitney U test will be used. When the data from the longer follow-up will be analyzed, repeated measurements ANOVA techniques will be used to analyze continuous variables and confounding factors will be taken into account in the analyses if needed.

Additional sub-group analyses will be performed for the data if it appears to be needed.

Two-tailed p-values will be used and p-values less than 0.05 will be considered statistically significant. The main analyses will be based on the intention-to-treat principle. Missing data will be excluded from the analyses. Statistical analyses will be performed using SAS System for Windows, Version 9.2 or later (SAS Institute Inc., Cary, NC).