

Efficacy and Safety of Endoscopic Sleeve Gastroplasty versus Laparoscopic Sleeve Gastrectomy in Obese Subjects with non-alcoholic steatohepatitis (NASH): Study protocol for a randomised controlled trial (TESLA-NASH study)

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Study protocol

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Abstract

Background : Non-alcoholic steatohepatitis (NASH) is a growing public health problem that affects more than 5% of the population. The standard treatment is weight loss with diet and exercise, which has been shown a histological and analytical improvement in patients capable to achieve a 5-10% reduction in their body weight. However, less than 25% of subjects achieve this goal. Bariatric surgery (BS) is the treatment of choice for its efficacy in obese patients. This intervention has resolved NASH in 85% of cases. However, bariatric endoscopy (BE) is presented as a therapeutic alternative with good results in terms of efficacy, long-term weight loss, and safety, decrease of adverse events.

Methods : The TESLA-NASH study is a randomized, controlled, open-label, unicentric clinical trial with a medical device. The aim of this study is to evaluate and compare the efficacy and safety of endoscopic sleeve gastropasty (ESG) versus laparoscopic sleeve gastrectomy (LSG) in liver histology improvement of patients with obesity +/- metabolic syndrome and NASH. A total of 30 patients will be randomized 1:1 to the experimental or control group.

Discussion : Gastric bypass surgery and restrictive surgical treatments have been successful improving metabolic syndrome, insulin resistance and liver histology of obese patients. Currently, endoscopic techniques which are less invasive, are being developed, showing fewer complications and lower sanitary cost, and gastric restrictions with similar characteristics to the traditional surgical method. The tubulization or vertical gastropasty with the OverStitch system (Apollo Endosurgery, Austin, TX, USA) is one of the most promising one. However, currently, any method is accepted as a standard treatment for NASH.

Trial registration : Clinical trial.gov: NCT04060368. Registered on 19 August 2019, <https://clinicaltrials.gov/ct2/show/NCT04060368> Protocol version: v 2.0, dated 15 nov 2019.

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