

Clinical Update

Updated on July 07, 2019



Study Objectives

Evaluate the Safety and Efficacy of the EndoZip™ procedure. Secondary endpoint is to evaluate the patients' weight loss results at 6 months.

Study Design

NitiNotes Surgical Ltd. is sponsoring an open label and single center study that is being performed by Dr. Lopez-Nava G. as the Principal Investigator, at the Bariatric Endoscopy unit of HM Sanchinarro University Hospital, Madrid, Spain.

The study includes 11 adult patients with BMI 30-40kg/m². Patients undergo Endoscopic gastroplasty performed with the EndoZip™ system, Safety of patients and the presence of stitches are evaluated by following up patients' well being and endoscopy at 1- and 6-months post procedure, respectively.

Safety Initial Results*

There were no intra-procedural nor serious adverse events related to the procedure up to this stage of the study.

Efficacy Initial Results*

Number of full thickness automatic sutures lines ranged between 2 to 4 per patient. Total Body Weight Loss, % Total Body Weight Loss and % Excess Body Weight Loss were: at 1 month 11.6 kg, 10.6% and 36.3%, respectively; at 3 months 14.8 kg, 13.5% and 46.5%, respectively and at 6 months 17.8 kg, 16.2% and 54.3%, respectively.

Study Status

Study enrollment and follow up period have ended. Study closer is anticipated by Sept. 2019.

Initial Results were presented in DDW May 2019 and can be found at:

[https://www.giejournal.org/article/S0016-5107\(19\)30502-4/fulltext](https://www.giejournal.org/article/S0016-5107(19)30502-4/fulltext) Sa1980: FIRST IN HUMAN RESULTS OF ENDOZIP, A NOVEL SUTURING BARIATRIC ENDOSCOPY PROCEDURE

** Please note that 2 patient were loss to follow up, thus were excluded from the final analysis.*