A PROSPECTIVE, RANDOMIZED, MULTICENTER STUDY COMPARING SEMS PLACEMENT WITH AND WITHOUT BILIARY SPHINCTERECTOMY IN PATIENTS WITH MALIGNANT BILIARY OBSTRUCTION

ES vs noES-1
Version 3 (06.07.15)

1 Summary

Title	**A PROSPECTIVE, RANDOMIZED, MULTICENTER STUDY COMPARING SEMS PLACEMENT WITH AND WITHOUT BILIARY SPHINCTERECTOMY IN PATIENTS WITH MALIGNANT BILIARY OBSTRUCTION**
Study coordinator: Dr Anderloni Protocol identifying number	**ES vs noES-1**
Protocol version date	Version 3 (06.07.15)
Background and rationale	Placement of biliary self expanding metal stent (SEMS) is indicated when malignant common bile duct obstruction is encountered [1]. Currently, there is still controversy regarding the use of endoscopic sphincterotomy (EST) before the placement of biliary stents. EST may facilitate insertion of self expandable metal stent (SEMS) and also help avert the development of pancreatitis from stent-related occlusion of the pancreatic duct. On the other hand, ES is also independently associated with pancreatitis, bleeding, and perforation. [2-5]. Latest European guidelines indicate that EST is not necessary for inserting single plastic or metal biliary stents [1], nevertheless a more recent meta analysis showed that ES may decrease the rate of PEP [5].
Population and patient selection criteria	All the patient referred for endoscopic retrograde cholangiopancreatography (ERCP) due to malignant bile duct obstruction.
Study design and study duration	Prospective randomized, multicenter study. 18 months.
Description of study treatment/product/intervention	All the patients will be randomly assigned to undergo ERCP with (Group A) or without (Group B) ES before biliary SEMS placement. All the endoscopic procedures will be performed by experienced endoscopist in the endoscopy suite. All the procedure will be conducted under deep sedation. SEMS placed will be fully covered.

Objectives	To assess the need for EST before SEMS placement in patients with malignant bile duct obstruction. To evaluate immediate (periprocedural) and delayed (30 days) post ERCP complications including pancreatitis, SEMS migration, bleeding and perforation.
Statistical methods, data analysis	A sample size analysis to detect superiority at 5% significance level and a power of 80% showed that 500 patients had to be enrolled in each group. Continuous variables such age will be reported in terms of their mean and range, and t-test will be done to test their main difference. X square test or Fisher exact test will be carried out for statistical analysis to compare rates of total complications between the two groups and rates of pancreatitis, bleeding, stent migration and perforation. Wilcoxon Mann-Withney test will be used for comparison of means between 2 continuous variables. A single-tailed P value of less than 0,05 is considered significant.
Study time table	*Project starting date: 15-7-2015* *Project completion of patients accrual: 15-10-2016* *Project completion of data collection: 15-11-2016* *Project data analysis: 15-2-2017* *Project presentation of scientific report: 15-4-2017*