

**STUDY PROTOCOL**

**1. ABSTRACT**

Currently, the most important outcome variables in Acute Pancreatitis (AP) are persistent organ failure (POF) and mortality, according to the physician point of view. These variables occur infrequently (10 and 5% respectively), therefore, studies designed to assess the effectiveness of new treatments for AP require a very large sample of patients. PROMS (Patient Reported Outcome Measures) has been defined as any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. Our group has developed a PROMS scale in a previous study. This scale focuses on symptoms that were found to be important for the patient. This allows to have a simple quantitative variable, relevant for the patient, that can be useful to test new treatments without the need for a huge sample size. The PROMISE study aims to validate the scale in an international prospective cohort of patients with AP. The sample size will be 384 patients ( $p = q = 0.50$ , defining a 95% confidence level and accepting a maximum error of 5%). The main variable for validation will be severity according to the revised Atlanta classification, the secondary variable will be the Quality of Life EORTC QLQ-C30 scale. Other variables for validation: presence of Systemic Inflammatory Response Syndrome (SIRS), persistent SIRS (> 48h), plasma levels of C-reactive protein at 48 hours, presence of local complications (acute peripancreatic fluid collections, pancreatic necrosis, peripancreatic necrosis), need for invasive treatment (endoscopic, percutaneous or surgical), admission to the Intensive Care Unit (ICU), hospital stay, organ failure, both transient (<48h) and persistent (> 48h), mortality and hospital re-admission.