

**Preventive pancreatic stents in the management of acute biliary pancreatitis (PREPAST trial): pre-study protocol for a multicenter, prospective, randomized, interventional, controlled trial.**

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**BACKGROUND:**

The outcome of the most common biliary form of acute pancreatitis has not changed even with the better described indications for early endoscopic intervention. It may be due to the fact that this intervention theoretically can cause further pancreatic injury or cannot always relieve the pancreatic duct obstruction. We hypothesize that maintaining the outflow of the pancreatic duct with preventive pancreatic stents at the early ERCP improves the outcome of acute biliary pancreatitis.

**METHODS/DESIGN:**

PREPAST is a prospective, randomized, controlled, multicenter trial. Patients with acute biliary pancreatitis with coexisting cholangitis are randomized to undergo urgent endoscopic intervention with or without pancreatic stenting within 48 h from the onset of pain, and in addition patients without signs of cholangitis but cholestasis are randomly allocated to receive conservative treatment or early endoscopic intervention with or without pancreatic stenting within 48 h from the onset of pain. Patients without acute cholangitis and signs of cholestasis receive conservative treatment. 230 patients are planned to be enrolled during a 48 months period from different centers. The primary endpoint is the outcome of acute biliary pancreatitis as described by the latest guidelines. Secondary endpoints include mortality data, and other variables not analyzed as a primary endpoint but related to the pancreatitis or the pancreatic stenting.

**DISCUSSION:**

The PREPAST trial is designed to show whether early endoscopic intervention with the usage of preventive pancreatic stenting improves the outcome of acute biliary pancreatitis. The study has been registered at the International Standard Randomised Controlled Trial Number (ISRCTN) Register (trial ID: ISRCTN13517695).