

WSACS 008 Study:
**A MULTICENTER OBSERVATIONAL STUDY
ON THE INCIDENCE OF INTRAABDOMINAL
HYPERTENSION IN PATIENTS WITH SEVERE
ACUTE PANCREATITIS, AND ITS EFFECT ON
OUTCOME.**

SPIRITstudy
(**S**evere **P**ancreatitis and **I**nt**R**aabdom**I**nal
hyper**T**ension)

Study protocol.

Date: 9/16/2008 3:50 PM

Summary of the study

Principal investigator: Jan J. De Waele, Ghent University Hospital, Belgium

Study centers and number of patients planned: 8-12 centers, 100-150 patients.

Participants (listed alphabetically):

B. De Keulenaere, Royal Darwin Hospital, Darwin, Australia

J. De Waele, University Hospital Ghent, Gent, Belgium

T. Dugernier, St. Pierre Hospital, Brussels, Belgium

P.F. Laterre, University Hospital St. Luc, Louvain, Belgium

M. Malbrain, ACZA, Antwerp, Belgium

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Study period

Enrollment of first patient: estimated January 2005

Objectives

Primary objective

To determine the incidence of intraabdominal hypertension in patients with severe acute pancreatitis, and evaluate the effect of the presence of intraabdominal hypertension on outcome (subject mortality, organ dysfunction, infection of pancreatic necrosis, requirement of surgical intervention)

Secondary objective

To determine the effect of abdominal decompression in patients with severe acute pancreatitis on outcome (subject mortality, changes in organ function, infection of pancreatic necrosis)

Study design

This is a prospective observational study.

Patient population

Male or female patients (age >18 years at the moment of screening) admitted to the ICU or an intermediate care unit, with a confirmed diagnosis of severe acute pancreatitis. Patients should be included within 7 days after the start of symptoms.

Duration of the study period

Patients will be studied until discharge from the hospital.

Intra-abdominal pressure (IAP) monitoring will continue from the start of the study (day 0) until discharge from the ICU.

Endpoints

Primary endpoint

- Development of intraabdominal hypertension.

Secondary endpoints

- Mortality (all cause)
- Development of multiple organ failure
- Change in organ dysfunction score
- Development of pancreatic necrosis
- Development of pancreatic or peripancreatic infection during hospital stay

- Requirement for an abdominal operation for either an abdominal compartment syndrome or other intraabdominal pathology (such as infection, bleeding or ischemia)

Statistical methods

The development of intraabdominal hypertension will be evaluated with logistic regression analysis.

The secondary endpoint mortality will be studied using a proportional hazards regression model. The effect of intraabdominal hypertension will be presented as the estimated hazard ratio, associated 95% confidence interval, and p value.

The secondary endpoint development of multiple organ failure will also be analyzed using a proportional hazards regression model. The effect of intraabdominal hypertension will be presented as the estimated hazard ratio, associated 95% confidence interval, and p value.

The secondary endpoint development of pancreatic infection will be analyzed using logistic regression analysis. The effect of intraabdominal hypertension will be presented as the estimated odds ratio, associated 95% confidence interval, and p value