Early and accurate diagnosis of disconnected Pancreatic duct syndrOme and pancreatic fistuLa in patients with Acute necRotizing pancreatitis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25785

Source
Nationaal Trial Register

Brief title
POLAR

Health condition

Acute pancreatitis, acute necrotizing pancreatitis, disconnected pancreatic duct syndrome

Sponsors and support

Primary sponsor: St. Antonius Hospital
Source(s) of monetary or material Support: St. Antoniusonderzoeksfonds, St. Antonius Hospital Nieuwgeein

Intervention

Outcome measures

Primary outcome

Incidence of disrupted or disconnected pancreatic duct

Secondary outcome

Clinical outcome of a disrupted or disconnected pancreatic duct (location and degree of parenchymal necrosis,location and degree of disruption of the pancreatic duct, microbiological cultures, type and number of interventions, drain in situ time, peri-procedural complications, overall complicaties, organ failure, mortality, lenght of hospital stay, lenght op ICU stay, number of readmissions, wuality of life).

Study description

Background summary

Disrupted or disconnected pancreatic duct syndrome and pancreatic fistula after necrotizing pancreatitis are a clinical dilemma in daily practice. The exact incidence and clinical outcomes are unclear and there is debate on which treatment should follow. The aim of this study is to provide insight in the actual incidence and clinical impact of disrupted or disconnected pancreatic duct syndrome in an unselected cohort of patients with acute necrotizing pancreatitis.

This multicentre prospective observational cohort study will include 98 adult patients with necrotizing pancreatitis. All patients with necrotizing pancreatitis will undergo a predefined, according to the current guidelines, work-up including MRCP. In case of percutaneous drainage, amylase level in drain fluids will be measured routinely. Follow-up will be one year and includes clinical follow-up and patient questionnaires. The primary outcome is incidence of disrupted or disconnected pancreatic duct syndrome and pancreatic fistula. Secondary endpoint is the clinical outcome of patients with and without a disrupted or disconnected pancreatic duct.

Study objective

This study will lead to early and accurate diagnosis of disrupted or disconnected pancreatic duct syndrome or pancreatic fistula in necrotizing pancreatitis. The obtained data will be used to develop a best-practice algorithm for the diagnosis and, eventually, treatment of disrupted or disconnected pancreatic duct syndrome and pancreatic fistula. This will hopefully lead to a shorter disease course with fewer complications, a faster recovery, lower health care costs and improved quality of life.

Study design

Follow-up will be one year and includes clinical follow-up and patient questionnaires, after one year primary and secondary outcomes will be measured.

Intervention

None

Contacts

Public
St. Antoniusziekenhuis, Dutch Pancreatitis Study Group
Hester Timmerhuis

+3188 3207051
Scientific
St. Antoniusziekenhuis, Dutch Pancreatitis Study Group
Hester Timmerhuis

+3188 3207051

Eligibility criteria

Inclusion criteria

- Patients over 18 years of age
- Patients with necrotizing pancreatitis as defined by the revised Atlanta Classification
- >3/4 weeks after onset of acute pancreatitis

Exclusion criteria

- Diagnosis of (or acute flare up of) chronic pancreatitis according to the M-ANNHEIM criteria
- Diagnosis of pancreatic carcinoma previous to the index admission or on the CT on which (peri)pancreatic necrosis is diagnosed
- Traumatic aetiology of pancreatitis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2019
Enrollment:	98
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8123
Other	MEC-U, St. Antoniusziekenhuis Nieuwegein : W019.086

Study results