# Acute Pancreatitis: A Comprehensive Exploration of immune lineages.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

# Summary

#### ID

NL-OMON46341

**Source** ToetsingOnline

Brief title APACHE

# Condition

• Gastrointestinal inflammatory conditions

**Synonym** Acute pancreatitis

**Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** subsidies

## Intervention

Keyword: acute pancreatitis, immune subsets

### **Outcome measures**

#### **Primary outcome**

The main study parameters are immune subsets which consist of a clustering of

peripheral blood leukocytes.

#### Secondary outcome

Secondary study parameters include serum urea, CRP, leukocyte counts,

mortality, morbidity, days of admission, prognostic scores, medical history,

medication, alcohol and drug use.

# **Study description**

#### **Background summary**

Acute pancreatitis (AP) is an inflammation of the pancreas with a mild disease course in 80% and severe course in 20% of the patients.1 Common causes of AP include chronic alcohol abuse or biliary stones, other causes include, but are not limited to, post-ERCP and idiopathic disease. Until now, studies into leukocytes in early AP have associated an increase in neutrophils with a more severe disease course. Yet, a more detailed assessment of major immune lineages is lacking. We hypothesize that patients with alcoholic, biliary and idiopathic AP have a specific composition of immune lineages and that immune subsets can be a prognostic tool to predict the severity of the disease course.

#### **Study objective**

The primary aim is to explore the system-wide leukocyte composition in order to identify and quantify immune subsets in patients with alcoholic, biliary and idiopathic AP. Secondary we aim to identify subsets prognostic for the severity of the disease course.

#### Study design

Observational study

#### Study burden and risks

Participating patients will be subjected to one extra blood draw (four tubes, 24 mL). In addition the study coordinator will have access to the medical chart of the patient. The medical treatment of participants is not different, participants will not be reimbursement.

# Contacts

**Public** Vrije Universiteit Medisch Centrum

de Boelelaan 1118 Amsterdam 1081HZ NL **Scientific** Vrije Universiteit Medisch Centrum

de Boelelaan 1118 Amsterdam 1081HZ NL

# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

## **Inclusion criteria**

Patients

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

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Suspected acute biliary, alcoholic or idiopathic pancreatitis

At least 2 out of 3 criteria of acute pancreatitis:

- Pain in upper abdomen
- Serum amylase and/or lipase >3x upper limit of normal (ULN)
- Signs of acute pancreatitis on CT or MR
- \* 18 years old

Provide informed consent; Healthy volunteers

A person is eligible to participate as healthy volunteer if they are considered to be healthy and if their age and gender matches with a patient included in this study.

## **Exclusion criteria**

Use of medications with possible immune-modulating effects (e.g., steroids or recent chemotherapy) Time from onset of abdominal pain to hospital admission >48 hours Established diagnosis of chronic pancreatitis Suspected cholangitis;Healthy volunteers Use of medications with possible immune-modulating effects (e.g., steroids or recent chemotherapy) Current or recent (in the last two weeks) infectious disease (i.e. influenza) Systemic diseases

# Study design

# Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2018
Enrollment:	80
Туре:	Anticipated

# **Ethics review**

Approved WMO	10.07.0010
Date:	18-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

# **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 CCMO ID NL65443.029.18