Autoimmune Pancreatitis: Long-term Outcome

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The objective of the study is to investigate the long-term clinical outcome of AIP with a minimum follow-up of two years.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Exocrine pancreas conditions
Study type	Observational invasive

Summary

ID

NL-OMON39923

Source
ToetsingOnline

Brief title
Autoimmune Pancreatitis: Long-term Outcome

Condition

- Exocrine pancreas conditions

Synonym
Autoimmune Pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autoimmune pancreatitis, outcome

Outcome measures

Primary outcome

To determine the prevalence of exocrine and endocrine insufficiency in AIP

patients.

Secondary outcome

To evaluate the following aspects of long-term outcome in AIP patients:

i. Mortality and cause of death

ii. Treatment over time: steroids, other drugs, response and relapses

iii. Extrapancreatic manifestations of AIP/IgG4-related disease

iv. Malignancy

v. Morphology (including changes over time in case multiple imaging sets are

available) of the pancreas on imaging

vi. Quality of life

Study description

Background summary

Autoimmune pancreatitis (AIP) is a distinct type of chronic pancreatitis (CP), which predominantly affects males in their fifth and sixth decades. AIP presents clinically as obstructive jaundice and less frequent with steatorrhea, diabetes mellitus and various extrapancreatic manifestations. This disease has several characteristic radiological features including diffuse enlargement of the pancreas and irregular narrowing of the main pancreatic duct which may be present but are not obligatory. Laboratory tests often reveal elevated serum levels of IgG, IgG4 and the presence of autoantibodies, but not in all cases. Steroids have to shown to be a highly effective therapy for AIP.4, 7-9 However, following steroid tapering or cessation, relapses are observed frequently (6-55%).10-12
Inflammation of the pancreas during an extended period can result in substantial fibrosis of the pancreas, causing permanent damage. This is frequently resulting in endocrine and/or exocrine insufficiency of the

pancreas.
Until now, long-term outcome has been described in relatively small series with a limited follow-up period. Especially the outcome with focus on pancreatic exocrine and endocrine function has been scarcely described in only retrospective series which are presumably subject to bias.

Study objective

The objective of the study is to investigate the long-term clinical outcome of AIP with a minimum follow-up of two years.

Study design

This is a prospective, cross-sectional study.

Study burden and risks

Burden:
Participation in this study requires withdrawal of blood and collection of a small amount of feces, both will take place once. The withdrawal of blood can take place during a routine visit at the attending gastroenterologist, so the subject will not have to travel far. If the patient does not have an appointment with the attending gastroenterologist, the principal investigator can visit the patient at home to withdraw the blood sample.
Feces will be send by mail, in a box which will be sent to the subject by us.
The subject will be asked to complete 2 questionaires concerning quality of life, and 1 questionaire concerning the course of the disease (AIP). This will take 1-1.5 hours. The questionaires will be send by mail, including a self-adressed envelope, with which the subject can return the questionaires.

Risks:
Withdrawal of blood can result in little pain, swelling and/or infection or a bruise. The collection of feces is not related with any risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The following patients are eligible for the study:
• All patients diagnosed with AIP according to the ICDC, Asian or HISORT criteria or based on post-surgery histology, a combination of unexplained pancreatic disease, biliary disease/extrapancreatic manifestations and either response to steroids or IgG4-positive serology.
•At least known for more than 2 years with a diagnosis of AIP
•Age > 18 years
•Signed informed consent

Exclusion criteria

The following patients are excluded from the study:
•Subjects who are unwilling or unable to understand the study and sign the informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2013
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-04-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL41656.078.12