Prevention of recurrent alcoholic pancreatitis by an optimally timed personalized multidisciplinary alcohol cessation support program

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22054

Source
NTR

Brief title
PANDA

Health condition

Acute alcoholic pancreatitis

Sponsors and support

Primary sponsor: St. Antonius Hospital, Nieuwegein
Source(s) of monetary or material Support: The study is funded by the Dutch Digestive Foundation (MLDS).

Intervention

Outcome measures

Primary outcome

Recurrent acute alcoholic pancreatitis

Secondary outcome

Cessation of alcohol use (defined as a modified AUDIT score of 0 at any time point during follow-up), clinically relevant reduction of alcohol use (defined as a modified AUDIT score ranging between 1 and 7 at any time point during follow-up), clinically relevant reduction of alcohol dependence (defined as a Short Alcohol Dependence Data (SADD) score between 1 and 9 at any time during follow-up), development of chronic pancreatitis, development of alcohol-related disease (liver steatosis, liver cirrhosis), mortality, quality of life, costs

Study description

Background summary

Rationale: The most important risk factor for pancreatitis recurrence and chronic pancreatitis in acute alcoholic pancreatitis is continuation of alcohol use, yet no cessation support program is applied in current practice.
Objective: To determine whether an optimally timed personalized multidisciplinary alcohol cessation support program can reduce pancreatitis recurrence in acute alcoholic pancreatitis as compared to standard practice.
Study design: Nationwide cluster randomized superiority trial. Participating centers will be randomized for the investigational management or standard practice in an equal allocation ratio and stratification according to hospital type (academic vs. non-academic).
Study population: Patients with a first episode of acute alcoholic pancreatitis (defined as an Alcohol Use Disorders Identification Test [AUDIT] score >7) without indication for referral to an addiction specialized physician (i.e. AUDIT > 15) will be included.
Intervention: The investigational management is based on the evidence-based general practice guideline on problematic alcohol use and consists of a program with six steps during hospital admission and after discharge, in which patients with acute alcoholic pancreatitis are individually supported in their alcohol cessation attempt.
Comparison: Care for acute alcoholic pancreatitis patients according to current practice.
Endpoints: The primary outcome is alcoholic pancreatitis recurrence. Secondary outcomes include cessation or reduction of alcohol use, development of chronic pancreatitis and quality of life. The follow-up period will comprise one year after admission.

Study objective

Implementation of an alcohol cessation support program reduces recurrence of acute alcoholic pancreatitis in patients with a first episode of acute alcoholic pancreatitis

Study design

Expected start data: December 2020

Inclusion period: 2 years
Follow-up period: 1 year after inclusion
Expected end date: December 2023

Intervention

The intestigational management is based on the evidence-based general practice guideline on problematic alcohol use and consists of a program with six steps during hospital admission and after discharge, in which patients with acute alcoholic pancreatitis are individually supported in their alcohol cessation attempt

Contacts

Public
Antonius Ziekenhuis
Noor Sissingh

0657117637
Scientific
Antonius Ziekenhuis
Noor Sissingh

0657117637

Eligibility criteria

Inclusion criteria

First episode of acute pancreatitis (according to the Revised Atlanta criteria), harmfull drinking (defined as AUDIT score>7), age of 18 or older and provided written informed consent

Exclusion criteria

Chronic pancreatitis, indication for referral to an addiction specialized phsyician (AUDIT>15), diagnosis of any etiology other than alcoholic after standard diagnostic work-up according to the IAP/APA evidence-based guidelines

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	20-08-2020
Application type:	First submission

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	NL8852
Other	Medical research Ethics Committees United (MEC-U) : W20.172

Study results