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

Gepubliceerd: 20-08-2020 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22054

Bron
NTR

Verkorte titel
PANDA

Aandoening

Acute alcoholic pancreatitis

Ondersteuning

Primaire sponsor: St. Antonius Hospital, Nieuwegein
Overige ondersteuning: The study is funded by the Dutch Digestive Foundation (MLDS).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Expected start data: December 2020
Inclusion period: 2 years
Follow-up period: 1 year after inclusion
Expected end date: December 2023

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

Antonius Ziekenhuis
Noor Sissingh

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	20-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8852
Ander register	Medical research Ethics Committees United (MEC-U) : W20.172

Resultaten