Pancreatitis and early omega-3-fatty acid infusion for reduction of organ failure and mortality: a multicenter randomized controlled trial (PLANCTON)

Published: 29-03-2022
Last updated: 14-09-2024

This study has been transitioned to CTIS with ID 2023-505220-57-03 check the CTIS register for the current data. The PLANCTON trial will investigate the effect of early intravenous OM-3 FAs on new onset organ failure and mortality in patients with...

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

Summary

ID

NL-OMON51853

Source
ToetsingOnline

Brief title
PLANCTON trial

Condition

- Exocrine pancreas conditions

Synonym
Inflammation of the pancreas

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Fresenius Kabi (bedrijf),Fresenius Medical Care

Intervention

Keyword: Acute pancreatitis, Mortality, Omega-3 fatty acids, Organ failure

Outcome measures

Primary outcome

Endpoints will be evaluated after the 180 days study period. The primary endpoint is a composite endpoint of new onset of organ failure (organ failure not present at randomization) and mortality.

Secondary outcome

Secondary endpoints are individual components of the composite endpoint, severe complications (([infected] pancreas necrosis, sepsis, pneumonia or cholangitis), quality of life, costs effectiveness, number of (surgical, endoscopic or radiologic) interventions, length of hospital and ICU stay.

Study description

Background summary

Acute pancreatitis (AP) is the most common gastrointestinal disorder requiring acute hospitalization. About 20% of all patients will develop severe acute pancreatitis (SAP) marked by a pro-inflammatory response and characterized by massive release of cytokines, which can cause the systemic inflammatory response syndrome (SIRS). SIRS increases the risk on (multi) organ failure and contributes to a mortality up to 30%.
Intravenous omega-3 fatty acids (OM-3 FAs) induce the production of anti-inflammatory cytokines and hereby ameliorate the inflammatory response. We hypothesize that the anti-inflammatory function of OM-3 FAs could attenuate SIRS and decrease the severity of SAP resulting in less (severe) organ failure and ultimately a lower mortality. The clinical implications of this mechanism is shown in a recent meta-analysis describing reduced mortality by the use of OM-3 FAs in 4 randomized trials in patients with acute pancreatitis. However,

the evidence was of low quality and a large multicenter trial on OM-3 FAs in predicted SAP is currently lacking. This could provide definitive proof for the beneficial effect of OM-3 FAs in acute pancreatitis.

Study objective

This study has been transitioned to CTIS with ID 2023-505220-57-03 check the CTIS register for the current data.

The PLANCTON trial will investigate the effect of early intravenous OM-3 FAs on new onset organ failure and mortality in patients with predicted SAP.

Study design

A multicenter randomized controlled trial

Intervention

Intravenous administration of a lipid emulsion (0.2g/kg/day) with OM-3 FAs, started within 24hrs of diagnosis of predicted SAP and within 72hrs after onset of symptoms of AP, for a total of 7 days.

Study burden and risks

The burden for participants in this study is limited. The risk of OM-3 FAs administration is estimated to be negligible because (serious) adverse events were not described in 14 randomized controlled trials in 551 patients (9 trials in 322 patients with sepsis and 5 trials in 229 patients with acute pancreatitis). Additionally, the known side effects of OM-3 FAs are rare (e.g. lipid overload syndrome and prolonged bleeding time) or of relative limited clinical importance (i.e. the taste of fish). The parenteral administration of OM-3 FAs and questionnaires can be marked as a (small) burden in addition to standard medical care. The benefit for (future) patients treated with OM-3 FAs could be substantial with a reduction in new onset organ failure and mortality.

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

• Predicted severe acute pancreatitis
• >=18 years old
• First episode of acute pancreatitis
• <24 hours after diagnosis of acute pancreatitis
• <72 hours after onset of symptoms of acute pancreatitis
• Able to read and/or understand the study procedures
• Able to give informed consent (or their legal representatives)

Exclusion criteria

• Intake of any OM-3 FAs-, krill and/or algae supplements in the week prior to complaints
• Participation in another intervention study for AP
• Organ failure on admission (Modified Marshall score >2)
• Recurrent pancreatitis
• Chronic pancreatitis
o Defined by the MANNHEIM criteria53
• Known allergy to fish oil, seafood, soja or egg products
• History or existing hyperlipidemia (laboratory proven triglycerides > 10.0 mmol/l)
• History of (severe) liver failure

• Impaired lipid metabolism may lead to accumulation of fatty acids in the blood, increasing risk of adverse events.
o Based on coagulation Factor V level or INR > 3 (without anti-coagulation by vitamine K)
• Ketoacidosis
• Acute thrombo-embolic disease
• Pregnancy or lactation
• Recent (< 6 months) myocardial infarction or strokeKnown coagulations disorders (e.g. Factor V Leiden, thrombocytopenia, etc.)
• Pancreatitis due to a (suspected) periampullary/ampullary or bile duct malignancy
• Other known or suspected malignancy that may interfere with the outcome(s) and/or execution of the PLANCTON trial
• Post ERCP-pancreatitis due to a (suspected) malignancy
• Patient is classified as moribund or expected to die within 24hours
o The intervention will not be able to affect this patient and is therefore useless to expose these patients.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-07-2022
Enrollment:	212
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Omegaven
Generic name:	Omegaven
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-05-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-07-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	05-12-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-01-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EU-CTR	CTIS2023-505220-57-03
EudraCT	EUCTR2022-000474-26-NL

Register	ID
CCMO	NL80570.091.22
Other	Nummer volgt, ingediend bij ISRTCN