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Does fishoil infusion reduce severe complications in predicted severe acute pancreatitis?

Submission date 04/02/2022	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/05/2022	**Overall study status** Ongoing	
Last Edited 04/06/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Acute pancreatitis is a condition where the pancreas becomes inflamed (swollen) over a short period of time. The pancreas is a small organ, located behind the stomach, that helps with digestion.
Acute pancreatitis (AP) is the most common gastrointestinal disorder requiring acute hospitalization. About 20% of all patients will develop severe acute pancreatitis often marked by a strong inflammatory response which can result in organ failure and severe complications, including mortality up to 30%.
Intravenous omega-3 fatty acids (fish oil) may ameliorate the inflammatory response. We hypothesize that the anti-inflammatory function of fish oil could attenuate reduce the severity of acute pancreatitis and improve outcome and survival.
The PLANCTON trial will investigate the effect of early fish oil infusion on new onset organ failure and mortality in patients with predicted severe acute pancreatitis.

Who can participate?
Adult patients with a first episode of predicted severe acute pancreatitis.

What does the study involve?
Patients will be randomized as early as possible after the diagnosis of acute pancreatitis (within 24 hours of diagnosis and within 72 hours after onset of symptoms) between fish oil or standard medical care.
When randomized for fish oil standard medical care is provided and intravenous administration of a lipid emulsion (0.2g/kg/day) with fish oil for a total of 7 days.

What are the possible benefits and risks of participating?
The burden for participants in this study is limited. The risk of fish oil administration is estimated to be negligible because (serious) adverse events were not described in published trials. Additionally, the known side effects of fish oil are rare. The intravenous administration of fish oil

and questionnaires can be marked as a (small) burden in addition to standard medical care. The benefit for (future) patients treated with fish oil could be substantial with a reduction in new onset organ failure and mortality in a very serious disease.

Where is the study run from?
The study will be run by the Dutch Pancreatitis Study Group (located at St. Antonius Hospital, Nieuwegein, the Netherlands).

When is the study starting and how long is it expected to run for?
January 2021 to February 2026

Who is funding the study?
Radboud Universitair Medisch Centrum (the Netherlands)
Fresenius Kabi (the Netherlands)

Who is the main contact?
Dr Martijn W.J. Stommel, Martijn.stommel@radboudumc.nl

Study website
https://pancreatitis.nl/plancton

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2022-000474-26, 2023-505220-57-03

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
80570

Study information

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

Acronym
PLANCTON

Study objectives
Based on the literature, there seems to be a relation in acute pancreatitis between (hyper) inflammation, SIRS, new onset of organ failure and mortality. Omega-3 fatty acids seem to have clinical beneficial effects through immunomodulation, supported by the decreased inflammatory biomarkers in patients with acute pancreatitis. Therefore, the following hypothesis was formulated:

Early intravenous administration of omega-3 fatty acids reduces the composite endpoint of new onset organ failure and/or mortality in patients with predicted severe acute pancreatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/05/2022, Radboud University Medical Center (P.O. Box 9101, 6500 HB Nijmegen, The Netherlands; +31 24 361 89 33; no email provided), ref: NL80570.091.22

Study design
Multicenter randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Predicted severe acute pancreatitis

Interventions
Participants are randomised to one of two groups using an online tool.

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

Control: Standard medical care

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Omegaven

Primary outcome measure
New onset of organ failure (organ failure not present at randomization) and mortality measured using patient notes during 6 months follow-up

Secondary outcome measures
1. Severe complications (([infected] pancreas necrosis, sepsis, pneumonia or cholangitis) measured using patient notes during 6 months follow-up
2. Quality of life measured using questionnaires at hospital discharge, 3 months and 6 months follow-up
3. Cost effectiveness measured using questionnaires at hospital discharge, 3 months and 6 months follow-up

4. Number of (surgical, endoscopic or radiologic) interventions measured using patient notes during 6 months follow-up
5. Length of hospital and ICU stay measured using using patient notes during 6 months follow-up

Overall study start date
01/01/2021

Completion date
01/02/2026

Eligibility

Key inclusion criteria
1. Predicted severe acute pancreatitis
2. ≥18 years old
3. First episode of acute pancreatitis
4. <24 hours after diagnosis of acute pancreatitis
5. <72 hours after onset of symptoms of acute pancreatitis
6. Able to read and/or understand the study procedures
7. Able to give informed consent (or their legal representatives)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
212

Key exclusion criteria
Current participant exclusion criteria as of 01/11/2023:
1. Intake of omega-3 fatty acids
2. Participation in another intervention study for acute pancreatitis
3. Organ failure on admission (Modified Marshall score >2)
4. Recurrent pancreatitis
5. Chronic pancreatitis. Defined by the MANNHEIM criteria
6. Known allergy to fish oil, seafood, soja, or egg products
7. History or existing hyperlipidemia (laboratory-proven triglycerides >10.0 mmol/l)
8. History of (severe) liver failure. Based on coagulation Factor V level or INR >3
9. (without anti-coagulation by vitamin K)
10. Ketoacidosis
11. Acute thrombo-embolic disease
12. Pregnancy or lactation

13. Recent (<6 months) myocardial infarction or stroke
14. Known coagulation disorders (e.g. Factor V Leiden, thrombocytopenia, etc.)
15. Pancreatitis due to a (suspected) periampullary/ampullary or bile duct malignancy
16. Other known or suspected malignancy that may interfere with the outcome(s) and/or execution of the PLANCTON trial
17. Post ERCP-pancreatitis due to a (suspected) malignancy
18. Patient is classified as moribund or expected to die within 24 hours

Previous participant exclusion criteria:
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2. Participation in another intervention study for acute pancreatitis
3. Organ failure on admission (Modified Marshall score >2)
4. Recurrent pancreatitis
5. Chronic pancreatitis. Defined by the MANNHEIM criteria
6. Known allergy to fish oil, seafood, soja, or egg products
7. History or existing hyperlipidemia (laboratory-proven triglycerides >10.0 mmol/l)
8. History of (severe) liver failure. Based on coagulation Factor V level or INR >3
9. (without anti-coagulation by vitamin K)
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11. Acute thrombo-embolic disease
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15. Patient is classified as moribund or expected to die within 24 hours

Date of first enrolment
15/07/2022

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
Denmark

Netherlands

Study participating centre
Radboud UMC
Nijmegen
Netherlands
6525 GA

Study participating centre
Amsterdam UMC
Amsterdam

Netherlands
1105 AZ

Study participating centre
MUMC+
Maastricht
Netherlands
6229 HC

Study participating centre
Erasmus MC
Rotterdam
Netherlands
3015 GD

Study participating centre
LUMC
Leiden
Netherlands
2333 ZA

Study participating centre
Bravis Hospital
Roosendaal
Netherlands
4708 AE

Study participating centre
Catharina Hospital
Eindhoven
Netherlands
5623 EJ

Study participating centre
CWZ
Nijmegen
Netherlands
6532 SZ

Study participating centre
Haga Hospital
The Hague
Netherlands
2545 AA

Study participating centre
Jeroen Bosch Hospital
Den Bosch
Netherlands
5223 GZ

Study participating centre
Meander Medical Center
Amersfoort
Netherlands
3813 TZ

Study participating centre
MST
Enschede
Netherlands
7512 KZ

Study participating centre
ZGV
Ede
Netherlands
6716 RP

Study participating centre
Hvidovre Hospital
Copenhagen
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2650

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.radboudumc.nl/EN/Pages/default.aspx

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Radboud Universitair Medisch Centrum

Alternative Name(s)
Radboudumc, Radboud University Medical Center, Radboud University Nijmegen Medical Center, RUNMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Funder Name
Fresenius Kabi

Alternative Name(s)
Fresenius Kabi AG, Fresenius Kabi Deutschland GmbH

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2027

Individual participant data (IPD) sharing plan
After the publication of all the results of the trial, anonymous data can be shared depending on the purpose of the application and the research question. Enquiries can be sent to Dr. M.W.J. Stommel, surgeon, Radboud University Medical Center, Nijmegen, The Netherlands (martijn.stommel@radboudumc.nl).

IPD sharing plan summary
Available on request