

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

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<b>Registration date</b> 17/05/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/04/2026	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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 May 2027

Who is funding the study?

1. Radboud Universitair Medisch Centrum (the Netherlands)
2. Fresenius Kabi (the Netherlands)

Who is the main contact?

Dr Martijn W.J. Stommel, [Martijn.stommel@radboudumc.nl](mailto:Martijn.stommel@radboudumc.nl)

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Martijn W.J. Stommel

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### Contact details

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### Type(s)

Scientific

### Contact name

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

2022-000474-26, 2023-505220-57-03

### **Protocol serial number**

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

### **Study type(s)**

Treatment

### **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(s)**

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

## **Key secondary outcome(s)**

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

## **Completion date**

01/05/2027

## **Eligibility**

### **Key inclusion criteria**

1. Predicted severe acute pancreatitis
2.  $\geq 18$  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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

0

**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)
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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. Patient is classified as moribund or expected to die within 24 hours

**Date of first enrolment**

15/07/2022

**Date of final enrolment**

02/03/2027

## **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  
Denmark  
2650

**Sponsor information****Organisation**

Radboud University Nijmegen Medical Centre

**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

## 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes