

# Prophylactic tributyrin supplementation in acute pancreatitis

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The main objective is to investigate the effect of oral tributyrin on plasma endotoxin in patients with acute pancreatitis.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment started
<b>Health condition type</b>	Bacterial infectious disorders
<b>Study type</b>	Interventional research previously applied in human subjects

## Summary

### ID

NL-OMON56163

### Source

ToetsingOnline

### Brief title

PARROT

## Condition

- Bacterial infectious disorders
- Exocrine pancreas conditions

### Synonym

acute pancreatitis; acute pancreatic inflammation

### Research involving

Human

## Sponsors and support

**Primary sponsor:** St. Antonius Ziekenhuis

**Source(s) of monetary or material Support:** Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten), St. Antonius Ziekenhuis

## Intervention

- Food (substances)

**Keyword:** Acute pancreatitis, Tributyrin

### Explanation

N.a.

## Outcome measures

### Primary outcome

The primary endpoint is plasma endotoxin concentration measured 3 days after randomisation.

### Secondary outcome

Secondary endpoints are toxicity, clinical outcomes, intestinal permeability, fecal SCFA concentrations, intestinal microbiota composition and systemic inflammatory response parameters (pulse, respiratory rate, temperature and white blood cell count), response of peripheral blood mononuclear cells (PBMCs) to stimulation with LPS, capacity of PBMCs to phagocytose/kill bacteria (*E. coli*).

## Study description

### Background summary

Acute pancreatitis (AP) is a common gastrointestinal disorder requiring acute hospitalization. Around 20% of patients that present with acute pancreatitis eventually develop severe complications such as (multiple) organ failure, (peri-) pancreatic necrosis, and secondary infections (i.e. infected necrosis, bacteraemia, pneumonia). The gut, especially the gut microbiome, is likely to play a role in development of infectious complications. Short-chain fatty acids (SCFAs) produced by the gut microbiota, such as butyrate, are known immunomodulators of the host response and exert local beneficial effects on the gut barrier and microbiota. Currently, there are no safe and effective therapies to mitigate disease severity that can be administered in the early phase of pancreatitis. We hypothesize that orally administered tributyrin, a pro-drug of butyrate, might beneficially influence disease progression in acute pancreatitis and may be useful as prophylaxis.

## **Study objective**

The main objective is to investigate the effect of oral tributyrin on plasma endotoxin in patients with acute pancreatitis.

## **Study design**

Phase IIa (Proof of concept) double-blind randomized placebo-controlled food supplement trial.

## **Intervention**

The intervention group receives three times daily 4g micro-encapsulated granules of tributyrin and the control group receives three times daily an equivalent volume of micro-encapsulated vegetable oil (i.e. placebo), for a total of maximum 14 days.

## **Study burden and risks**

The blood sampling at inclusion, and day 3 and 7 of treatment are preferably combined with regular blood sampling. Participants may experience minor discomfort from rectal swabs. Phase 1 studies with oral tributyrin conducted in patients with solid tumors did not report serious adverse events. However, there is a risk of unanticipated adverse events in our target population. An independent data safety and monitoring board (DSMB) will discuss all reported serious adverse events (SAE\*s).

## **Contacts**

### **Scientific**

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### **Public**

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## Trial sites

### Trial sites in the Netherlands

St. Antonius Ziekenhuis	
Target size:	52
Reinier de Graaf Groep	
Target size:	40

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

acute pancreatitis, defined as two or more of the following criteria:

- abdominal pain
- serum amylase or lipase more than three times the upper limit
- evidence of acute pancreatitis on abdominal CT

### Exclusion criteria

- Pancreatitis due to ERCP, malignancy, trauma
- Post-operative pancreatitis
- Intra-operative diagnosis
- Immunocompromised patients (history or current immunosuppressive treatment such as chemotherapy, radiotherapy, longer use of immunosuppressive medication or recent high doses, immunocompromised illness\* such as AIDS, leukemia, lymphoma)
- Pregnancy and/or lactation
- Age <18 years old
- History of chronic (MANNHEIM criteria) pancreatitis
- >72 hours since onset of symptoms
- Episode of acute pancreatitis within the last year, or a history of three or

more episodes of acute pancreatitis

## Study design

### Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment started
Start date (anticipated):	12-02-2024
Enrollment:	92
Duration:	3 months (per patient)
Type:	Actual

### Medical products/devices used

Product type:	N.a.
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### IPD sharing statement

**Plan to share IPD:** Undecided

#### Plan description

N.a.

## Ethics review

Approved WMO	
Date:	11-05-2023

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-07-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-05-2025
Application type:	Amendment
Review commission:	MEC-U

## 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

ClinicalTrials.gov

CCMO

Research portal

### ID

NCT06147635

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