# Precision use of Antibiotics in Infected Necrotizing Pancreatitis

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Gastrointestinal inflammatory conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56749

**Source**
ToetsingOnline

**Brief title**
PIANO

### Condition

- Gastrointestinal inflammatory conditions
- Bacterial infectious disorders

**Synonym**
Acute necrotizing pancreatitis; acute pancreatitis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** acute necrotizing pancreatitis, antibiotic resistance, antimicrobial stewardship, infected necrosis

## Outcome measures

### Primary outcome

The primary endpoint is a composite of mortality and major complications

between index admission and 6 months follow-up. Major complications are defined

as new onset organ failure and necessity of invasive intervention(s) for

infected pancreas necrosis.

### Secondary outcome

Secondary endpoints include antimicrobial use, infections with multi-drug

resistant microorganisms, development of major infections and other

complications, health care utilization, quality of life and cost-effectiveness.

# Study description

### Background summary

Antimicrobial treatment is a key part of treatment of infected necrotizing pancreatitis (IPN), alongside supportive care and drainage interventions. There are, however, no recommendations in current guidelines regarding the choice, timing and duration of antimicrobials for IPN. A recent observational cohort study showed that antimicrobial treatment for patients with necrotizing pancreatitis is currently very heterogeneous and often inappropriate. The antimicrobial stewardship approach aims to improve the quality of antimicrobial use in order to improve patient outcomes, curb the rapidly growing rise in antimicrobial resistance and reduce unnecessary costs. A best-practice protocol based on current evidence and antimicrobial stewardship principles is expected to lead to more appropriate use of antibiotics in patients with (infected) necrotizing pancreatitis.

### Study objective

The primary objective is to determine whether implementation of a best-practice protocol focused on antimicrobial stewardship in Dutch hospitals is non-inferior compared to standard care on mortality and major complications in patients with acute necrotizing pancreatitis.

### Study design

A nationwide, noninferiority, parallel group, cluster-randomized trial. Aproximately 30 clusters of at least two hospitals will be randomized to the intervention (a best-practice protocol focussed on antimicrobial stewardship) or usual care in a 1:1 allocation ratio.

### Intervention

Implementation of a best-practice protocol on cluster level, targeted at clinical staff involved in the treatment of necrotizing pancreatitis. During a two-month transition phase, intervention clusters will engage in the implementation procedure including educational and consensus meetings, an e-learning platform and clinical decision tool. The best-practice protocol consists of recommendations to improve and standardize the antimicrobial treatment strategy for necrotizing pancreatitis. These recommendations are based on antimicrobial stewardship principles, the best available evidence and a worldwide Delphi consensus survey. A final component of the intervention is the evaluation of the implementation strategy and assessment of compliance with the best-practice protocol.

### Study burden and risks

Due to the intervention at cluster level, patients are not directly involved in the trial. The burden of participation concerns the time investment that is necessary to the complete these questionnaires. No additional interventions or tests associated with participation in the study. The anticipated benefits of the best-practice protocol include a reduced risk of colonization and infection with multi-drug resistant microorganisms, shorter hospital stay and less invasive interventions due to more successful conservative management of infected necrotizing pancreatitis.

## 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

- Age >= 18 years
- Hospitalized patient diagnosed with acute pancreatitis according to the revised Atlanta classification
- Signs of pancreatic or peripancreatic necrosis on imaging
- Written informed consent

## Exclusion criteria

- Patients with a current pancreatic carcinoma
- Patients with (an acute flare-up of) chronic pancreatitis according to the M-ANNHEIM criteria

# Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Health services research

### Recruitment

NL

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2024 |
| Enrollment: | 288 |
| Type: | Anticipated |

## Ethics review

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| Approved WMO Date: | 14-05-2024 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 12-09-2024 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## 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 |
| --- | --- |
| CCMO | NL86193.018.24 |