

Probiotic prophylaxis in patients with predicted severe acute pancreatitis: placebo-controlled randomised clinical trial. Dutch Acute Pancreatitis Study Group

Submission date 31/05/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 14/07/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/04/2009	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
03/169

Study information

Scientific Title

Acronym

PROPATRIA

Study objectives

Infectious complications are the major cause of death in acute pancreatitis. Small bowel bacterial overgrowth and subsequent bacterial translocation are held responsible for the vast majority of these infections. Goal of this study is to determine whether selected probiotics are capable of preventing infectious complications without the disadvantages of antibiotic prophylaxis; antibiotic resistance and fungal overgrowth.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study is conducted in accordance with the principles of the Declaration of Helsinki and 'good clinical practice' guidelines. The independent ethics committee of all 15 participating hospitals approved the final protocol. Oral and written informed consent in form is obtained from the patient before inclusion in the trial.

Primary study design

Interventional

Study design

Multicentre placebo controlled randomised trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute pancreatitis

Interventions

Patients are randomly assigned to receive either live multispecies probiotics (6 strains, Ecologic 641) or placebo for 4 weeks by nasojejunal tube. Treatment is started within 72 hours after onset of abdominal pain.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Probiotics

Primary outcome(s)

Total number of infectious complications.

Key secondary outcome(s)

1. Costs
2. Hospital stay
3. Intensive care unit (ICU) stay
4. Mortality
5. Morbidity

Completion date

01/12/2006

Eligibility**Key inclusion criteria**

Patients of all Dutch University Hospitals and major non-University Hospitals who are admitted with predicted severe acute pancreatitis.

Added Feb 2008:

1. Age equal to or above 18 years
2. First episode of acute pancreatitis
3. Written and oral informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Added Feb 2008:

1. Post-ERCP pancreatitis
2. Malignancy
3. Infection/sepsis caused by a second disease
4. Intra-operative diagnosis
5. Immunocompromised patients
6. Use of probiotics during admission

Date of first enrolment

01/03/2004

Date of final enrolment

01/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

UMC Utrecht

Utrecht

Netherlands

3584 CX

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Government

Funder Name

Senter (Netherlands) - <http://www.senter.nl>, an agency of the Ministry of Economic Affairs

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/02/2008		Yes	No
Protocol article	protocol	29/09/2004		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes