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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

Registration date
14/07/2004

Overall study status
Completed

Last Edited
27/04/2009

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pancreatitis.nl/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Multicentre placebo controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Total number of infectious complications.

Secondary outcome measures
1. Costs
2. Hospital stay
3. Intesive care unit (ICU) stay
4. Mortality
5. Morbidity

Overall study start date
01/03/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

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)

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Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	29/09/2004		Yes	No
Results article	results	23/02/2008		Yes	No