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Can Lactobacillus plantarum 299v in fermented oat meal gruel prevent overgrowth of Clostridium difficile in the Gastrointestinal (GI) tract in antibiotic treated critically ill patients? [Kan Lactobacillus Plantarum 299v i fermenterad havrevälling motverka överväxt av Clostridium Difficile i magtarmkanalen hos antibiotikabehandlade kritiskt sjuka patienter?]

Submission date
12/09/2007

Recruitment status
No longer recruiting

Registration date
17/09/2007

Overall study status
Completed

Last Edited
02/09/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PROMAX 2

Study information

Scientific Title
Can Lactobacillus plantarum 299v in fermented oat meal gruel prevent overgrowth of Clostridium difficile in the Gastrointestinal (GI) tract in antibiotic treated critically ill patients? [Kan Lactobacillus Plantarum 299v i fermenterad havrevälling motverka överväxt av Clostridium Difficile i magtarmkanalen hos antibiotikabehandlade kritiskt sjuka patienter?]

Study objectives
By giving a probiotic bacterium with known ability to establish in the GI tract also in antibiotic-treated critically ill there will be a reduction of the incidence of Clostridium difficile in Intensive Care Unit (ICU) patients on antibiotics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Final ethical approval received on the 8th October 2001 from:
1. The Human Ethics Committee at Lund University (ref: LU 676-00)
2. The Human Ethics Committee at the University of Gothemburg (ref: Gbg M 123-01)

Study design
Randomised, double blind placebo controlled multi-centre study

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

Overgrowth of C. difficile in GI tract of antibiotic-treated ICU patients

Interventions
1. Active group receives a fermented oatmeal formula containing 8 x 10^8 colony forming units (cfu)/ml of Lactobacillus plantarum 299v
2. Control product contains no bacteria. Lactic acid has been added to reach the same pH as the active product

The patients are given six 100 ml doses of the study product at twelve hours intervals and then 50 ml twice a day as long as they are in the ICU.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lactobacillus plantarum 299v

Primary outcome measure
To study the impact of L plantarum 299v on emerging cases of C. difficile in ICU patients compared to those receiving a placebo product.

The primary outcome is validated over the whole period in the Intensive Care Unit and cultures from faeces are taken twice a week. Overgrowth or colonisation with C difficile can appear in the range from a few days to several weeks of antibiotic treatment and even after the medication has ended.

Secondary outcome measures
1. Study gut barrier function
2. Recovery rates of L plantarum 299v, and other effects on the gut microbiota
3. Systemic infections
4. Immune response, as White Blood Cell count (WBC), C-Reactive Protein (CRP) and cytokines (Tumour Necrotising Factor [TNF], Interleukin-1 [IL-1], Interleukin-6 [IL-6] and Interleukin-10 [IL-10])
5. Influence on metabolic parameters

Gut permeability is tested at inclusion day (day 1) and on day 4 so outcome is measured on study day 4. Faecal samples are taken at enrolment and then twice a week. Recovery of added bacteria are validated for the whole Length of Stay (LOS). Due to impaired function of the bowel in critically ill patients passage time through the gut varies so much that the whole LOS will be used to evaluate colonisation with L plantarum 299v. Microbiological cultures (as tests for systemic infections) are taken on clinical grounds or at least once a week and results are summarised for the whole LOS. Infectious, inflammatory and metabolic parameters are followed by daily blood tests throughout the stay in the ICU. Daily comparisons will be performed for the active treatment and placebo groups.

Overall study start date
01/12/2001

Completion date
15/09/2007

Eligibility

Key inclusion criteria
1. 18 years or older
2. Critically ill, defined by a presumed need of intensive care for three days or more
3. Not have any known positive test for C. difficile within the week before enrolment
4. Be anticipated to tolerate enteral feeding
5. Starting within 24 hours from ICU admission

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
44

Key exclusion criteria
1. Not be allergic to any of the components in the study product
2. If entereral feeding (including study product) is not started within 24 hours
3. Not be moribund

Date of first enrolment
01/12/2001

Date of final enrolment
15/09/2007

Locations

Countries of recruitment
Sweden

Study participating centre

Department of Anaesthesiology and Intensive Care
Lund
Sweden
SE-221 85

Sponsor information

Organisation
Probi AB (Sweden)

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Sponsor type
Industry

Website
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ROR
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Funder(s)

Funder type
Industry

Funder Name
Probi AB (Sweden)

Funder Name
Region Skane (Sweden)

Funder Name

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?
Results article		01/09/2008	02/09/2021	Yes	No