

Probiotic Approach to Combat multi-resistant Enterocci: a cross-over clinical trial on the effect of probiotics on nosocomial spread of CC17 *Enterococcus faecium*

Submission date
30/05/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/05/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
04/07/2019

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

06-274

Study information

Scientific Title

Probiotic Approach to Combat multi-resistant Enterocci: a cross-over clinical trial on the effect of probiotics on nosocomial spread of CC17 Enterococcus faecium

Acronym

PACE

Study objectives

Probiotics, defined as microbial food supplements that improve intestinal colonisation resistance, will decrease incidence and prevalence of gut colonisation with CC17 ampicillin-resistant enterococcus faecium (ARE) in hospitalised patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The trial was approved by the Medical Ethical Commission (METC) of the University Medical Center Utrecht on the 6th March 2007 (ref: 06-274).

Study design

Prospective cohort study existing of two periods (period A with no intervention and period B with probiotics as intervention) executed in two wards in a cross-over design.

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Ampicillin-resistant Enterococcus faecium (ARE) infection

Interventions

The name of the probiotic product that is used in this trial is Ecologic® AAD, a multi-species probiotic powder, containing ten species (Bifidobacterium bifidum, Bifidobacterium lactis (2x), Enterococcus faecium, Lactobacillus acidophilus (2x), Lactobacillus paracasei, Lactobacillus plantarum, Lactobacillus rhamnosus, Lactobacillus salivarius) at 10^9 cfu/gr, which will be added

to the diet of all admissions in study period B, the intervention period. Winclove Bio Industries BV has been producing multi-species probiotic powders for almost fifteen years. The lactic acid bacteria used are all commercially available in other products. All components are legally admitted as food additives or food components. The product that will be used in this study, Ecologic® AAD, is notified as dietary medical food for special medical purposes.

Probiotics are considered to be safe for the host. In the European workshop on the safety aspects of lactic acid bacteria used as probiotics in 1999, it was concluded that the available evidence does not indicate any health risk posed by ingestion of lactic acid bacteria. The long history of consumption, the available epidemiological data, clinical trials and acute toxicity studies all suggest that lactic acid bacteria, commonly occurring in fermented and dairy foods (green olives, sauer-kraut, yoghurt, cheese, etc.) and used in current probiotics (lactobacilli and bifidobacteria added to yoghurt, etc.), are safe. In addition antibiotic susceptibility testing ensures that the used lactic acid bacteria are unlikely to influence undesirable antibiotic gene transfer cascades in vivo and are not expected to cause any risk for human health with regard to antibiotic resistance. In contrast, we hypothesise that probiotics can reduce the spread of multi-resistant nosocomial pathogens like CC17 *E. faecium* by preventing intestinal colonisation and thereby will contribute to reducing occurrence of nosocomial infections and possibilities for horizontal transfer of resistance genes.

In the intervention period twice a day a sachet containing 5 gram of the probiotic powder has to be consumed, preferably on an empty stomach in the morning and before going to sleep. When oral antibiotics are used, probiotics should be given at least two hours before or after antibiotics. The nursing staff will dissolve the probiotic powder in lucid water and will sign a special form when the patient has taken the product. In the case of gastric and duodenal tubes the dissolved product can be given via the tube. The product will be given as soon as oral consent is given after admission to one of the study wards until discharge of the ward.

During the admission patients are screened for ARE colonisation by a perianal swab on admission, before discharge and twice weekly during admission. When a patient is discharged from the ward, no further follow-up will take place.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Probiotics

Primary outcome measure

The difference in acquisition rate of rectal ARE-colonisation between periods A and B. Acquisition of ARE-colonisation is defined as a patient that is not colonised on admission that acquires colonisation during admission. This is measured by a perianal swab within 48 hours after admission and within 72 hours before discharge. At the end of the study, the total acquisition rate of period A is compared with the total acquisition rate of period B to investigate if there is a difference. This analysis is performed for both separate wards.

Secondary outcome measures

The difference in prevalence of rectal ARE-colonisation between periods A and B. Twice weekly all patients are screened for ARE-colonisation. On these days the prevalence of ARE-colonisation can be determined. Because of natural fluctuations, these prevalences will differ per day. Therefore, at the end of the study the mean prevalence and the distribution of ARE-colonisation in period A will be compared with period B to investigate if there is a difference that can be explained by the use of the investigational product. This analysis is performed for both separate wards.

Overall study start date

01/05/2007

Completion date

01/02/2008

Eligibility

Key inclusion criteria

All admissions on two wards (gastroenterology/nephrology and geriatrics) of the University Medical Centre Utrecht, where ARE colonisation is endemic.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

640

Total final enrolment

661

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/05/2007

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
Utrecht
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Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.umcutrecht.nl/zorg/>

ROR

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

Funder(s)

Funder type

Government

Funder Name

European Union (Belgium)

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	results	01/07/2010	04/07/2019	Yes	No