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Probiotic Approach to Combat multi-resistent 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

Registration date
30/05/2007

Overall study status
Completed

Last Edited
04/07/2019

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

Contact name
Ms M.J.A. de Regt

Contact details
University Medical Centre Utrecht (UMCU)
Department of Medical Microbiology
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 2505006
m.deregt@umcutrecht.nl

Additional identifiers

Protocol serial number
06-274

Study information

Scientific Title
Probiotic Approach to Combat multi-resistent 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

Study type(s)
Treatment

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 de 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 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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR

https://ror.org/04pp8hn57

Funder(s)

Funder type
Government

Funder Name
European Union (Belgium)

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