Probiotic Approach to Combat multi-resistant Enterococci: A Cross-over Trial on the Effect of Probiotics on Nosocomial Spread of CC17 Enterococcus faecium

Published: 25-04-2007
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To determine the effect of probiotics (microbial food supplements) on acquisition rates and colonization prevalence of CC17 ARE in two wards where ARE-colonization is endemic.

Ethical review	-
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON30711

Source
ToetsingOnline

Brief title
PACE

Condition

- Bacterial infectious disorders

Synonym
colonization; carriership

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: E. faecium, multi-resistant, nosocomial, probiotics

Outcome measures

Primary outcome

Primary endpoint: the difference in acquisition rate of intestinal

ARE-colonization between periods A and B.

Secondary outcome

Secondary endpoint: the difference in endemic prevalence of intestinal

ARE-colonization between periods A and B.

Study description

Background summary

During the last decade Enterococcus faecium has emerged in the University Medical Centre Utrecht as a nosocomial pathogen with cumulating antimicrobial resitance, a trend seen in hospitals worldwide. In the E. faecium population structure, based upon MLST, epidemic and most invasive isolates cluster in clonal complex-17 (CC17), characterized by ampicillin resistance. Besides the risk of infection, intestinal colonization with CC17 E. faecium of hospitalized patients forms a major threat for human health care as a reservoir of horizontal transferable antibiotic resistance genes.
We hypothesize that probiotics, defined as microbial food supplements that improve intestinal colonization resistance, will decrease incidence and prevalence of gut colonization with CC17 ampicillin resistant E. faecium (ARE) in hospitalized patients. As a result nosocomial infections, patient-to-patient transmission and possibilities for horizontal transfer of antibiotic resistance genes will reduce as well.

Study objective

To determine the effect of probiotics (microbial food supplements) on acquisition rates and colonization prevalence of CC17 ARE in two wards where ARE-colonization is endemic.

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.

Intervention

During period B probiotics are added to the diet of all admissions to the study ward twice daily. During period A patients will not receive probiotics

Study burden and risks

ARE prevalence and acquisition rates will be determined upon surveillance swabs. No extra burden will be added by this study. There are no risks associated with participation. The probiotic product as in this study has been used in another clinical trial and is considered to be safe.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All admissions during the study periods on 2 wards with a high prevalence of intestinal ARE-colonization: the geriatric and gastroenterology/nephrology wards of the UMCU.

Exclusion criteria

None

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-02-2007
Enrollment:	640
Type:	Anticipated

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL14948.041.06