Probiotica Approach to Combat multi-resistent Enterocci: A Cross-over Clinical Trial on the Effect of Probiotics on Nosocomial Spread of CC17 Enterococcus faecium

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25438

Source
Nationaal Trial Register

Brief title
PACE

Health condition

infection control; nosocomial; ARE; Enterococcus faecium; antimicrobial resistance; epidemiology; probiotics

infectie preventie; nosocomiaal; ARE, Enterococcus faecium, antibiotica resistentie, probiotica

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: European Union

Intervention

Outcome measures

Primary outcome

Difference in acquisition rate of perianal ARE-colonization between the probiotic period and the control period

Secondary outcome

Difference in prevalence of perianal ARE-colonization between the probiotic period and the control period

Study description

Background summary

Rationale:
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.
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.
Study population:
All admissions during the study periods on two wards where intestinal ARE-colonization is endemic: gastroenterology/nephrology and geriatrics.
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.

Methods:
ARE surveillance swabs will be analyzed for presence of ARE. Patient specific demographics and clinical data will be recorded.
Main study parameters/endpoints:
Primary endpoint:
the difference in acquisition rate of perianal ARE-colonization between periods A and B.
Secondary endpoint:
the difference in endemic prevalence of perianal ARE-colonization between periods A and B.
Nature and extent of the burden:
ARE prevalence and acquisition rates will be determined upon surveillance swabs. No extra burden will be added by this study.
Risks associated with participation:
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.

Study objective

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.

Intervention

Probiotics, twice daily

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

No exclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	640
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-04-2007
Application type:	First submission

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
NTR-new	NL937
NTR-old	NTR962
Other	: 06-274
ISRCTN	ISRCTN58761709

Study results