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

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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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON25438

**Bron**
NTR

**Verkorte titel**
PACE

**Aandoening**

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

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

### Ondersteuning

**Primaire sponsor:** University Medical Center Utrecht
**Overige ondersteuning:** European Union

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksproduct en/of interventie

Probiotics, twice daily

## Contactpersonen

### Publiek

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### Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No exclusion criteria

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Cross-over |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-05-2007 |
| Aantal proefpersonen: | 640 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 19-04-2007 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL937 |
| NTR-old | NTR962 |
| Ander register | : 06-274 |
| ISRCTN | ISRCTN58761709 |

# Resultaten