Effect of a multispecies probiotic on bowel management in patients with spinal cord injury after use of antibiotics

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To investigate whether the use of a probiotic can decrease antibiotic associated diarrhoea and positively influences the bowel management regimen of SCI patients treated with antibiotics.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON47019

Source
ToetsingOnline

Brief title
Effect of probiotics on bowel management in SCI

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Heliomare
Source(s) of monetary or material Support: eigen middelen Heliomare,Winclove

Intervention

Keyword: Antibiotic-associated diarrhoea, Antibiotics, Probiotics, Spinal cord injury

Outcome measures

Primary outcome

Antibiotic associated diarrhoea, defined as three or more liquid stools

(Bristol stool scale score 5, 6 or 7) per day for three or more days.

Secondary outcome

Time to reach proper bowel management, defecation frequency, faecel

consistency, quality of life.

Study description

Background summary

Spinal Cord Injury (SCI) often results in a neurogenic bowel and frequent requirement of antibiotic treatment. Therefore, these patients are at high risk of developing antibiotic related bowel problems, such as diarrhoea. Probiotics have clearly shown to prevent/treat antibiotic associated diarrhoea but studies investigating the effect in SCI patients are lacking.

Study objective

To investigate whether the use of a probiotic can decrease antibiotic associated diarrhoea and positively influences the bowel management regimen of SCI patients treated with antibiotics.

Study design

Double-blind randomized placebo-controlled study

Intervention

Probiotics or placebo

Study burden and risks

The probiotic mixture is available on the Dutch market and several international markets (Austria, Germany, Russia, Slovenia, Norway, Ukraine and Greece) for the reduction of antibiotic associated side effects . The lactic acid bacteria in the mixture carry the European Union Qualified Presumption of Safety (QPS) or have an extensive safety record. No side effects are expected. No invasive measurements are performed.

Contacts

Public
Revalidatiecentrum Heliomare

Relweg 51
Wijk aan Zee 1949EC
NL
Scientific
Revalidatiecentrum Heliomare

Relweg 51
Wijk aan Zee 1949EC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients should be confirmed with the diagnosis of spinal cord injury (SCI), first be admidded to a rehabilitation center after the occurrence of the SCI, aged between 18 and 75 years, and requiring treatment with antibiotics.

Exclusion criteria

Exclusion criteria
- Known gastro-intestinal diseases
- Abdominal surgery within a year prior to study
- (Previous) radiotherapy or chemotherapy
- Severe auto immune diseases such as SLE and Sjogren
- Patients suffering from severe acute pancreatitis, multiple organ failure (MOF) or sepsis
- Patients receiving enteral feeding with the exception of nasogastric feeding
- Excessive alcohol intake (> 15 consumptions per week)
- (Planned) pregnancy or lactation
- Use of pre-, probiotics in the month before and during the study
- Use of antibiotics in the two weeks before the study
- More than one antibiotic treatment in the 6 month prior to the study.
- Previous participation in this study design
- Duration of antibiotics use longer than 10 days
- Antibiotic use of nitrofurantoin or trimethoprim, nitrofurantoine, flucloxacilline (very few to no antibiotics associated diarrhea has been shown in the general population)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2017
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	Nederlands Trial Register (in behandeling)
CCMO	NL57438.029.16