Effect of probiotics on bowel management in SCI

No registrations found.

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

Summary

ID

NL-OMON21378

Source
Nationaal Trial Register

Health condition

Spinal cord injury
Dwarslaesie
Faecal incontinence
Diarree
Antibiotics
Antibiotica
Probiotics
Probiotica

Sponsors and support

Primary sponsor: Heliomare Rehabiliation Wijk aan Zee
Reade Center for Rehabilitation and Rheumatology Amsterdam
Source(s) of monetary or material Support: Heliomare Rehabiliation Wijk aan Zee
Winclove Probiotics B.V.

Intervention

Outcome measures

Primary outcome

Incidence of faecal incontinence, defined by frequency, consistency, (un)wanted defecation, measured by the Bristol Stool Scale.

Secondary outcome

Quality of life, nausea.

Study description

Background summary

Antibiotic-associated diarrhea is a common complication in antibiotic use in patients with a spinal cord injury. Diarrhea primarily leads to feelings of general discomfort and, as as a result, patients might be delayed in their rehabilitation after spinal cord injury. The objective of this study is to investigate whether the use of probiotics can decrease faecal incontinence and positively influence the bowel management regimen in inpatients with a spinal cord injury treated with antibiotics. The use of probiotics will be double-blind controlled with a placebo. The primary outcome that will be compared between the intervention and placebo group is the incidence of faecal incontinence, defined by frequency, consistency, and (un)wanted defecation. Secondary outcome measures are quality of life and nausea.

Study objective

In this double-blind randomized placebo-controlled trial, we hypothesize to observe a reduced incidence of antibiotic associated diarrhae (AAD) in inpatients with a spinal cord injury (SCI) during the intake of probiotics, in comparison to a placebo, when antibiotic treatment is provided.

Study design

T0 = start of intervention: start use of antibiotics together with probiotics or the placebo

T1 = last day of use of antibiotics (between 5 and 10 days after T0)

T2 = last day of use of probiotics (2 weeks after T1)

T3 = end of follow-up period (2 weeks after T2)

Intervention

Participants will be randomly assigned to receive both an antibiotic treatment and Ecologic® AAD, or an antibiotic treatment and a placebo. Subjects will receive either probiotic or placebo for 26-31 days (depending on the length of antibiotic treatment; 5-10 days); starting

together with the antibiotic treatment and ending three weeks after cessation.

Contacts

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Eligibility criteria

Inclusion criteria

- Confirmed diagnosis of SCI

- First admission to a rehabilitation center after the occurrence of SCI.

- Age between 18-75 years

- Requiring treatment with antibiotics

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 14 days

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2016
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-04-2016
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	NL5687
NTR-old	NTR5831
Other	: ABR57438

Study results