Effect of probiotics on bowel management in SCI

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21378

Bron
Nationaal Trial Register

Aandoening

Spinal cord injury
Dwarslaesie
Faecal incontinence
Diarree
Antibiotics
Antibiotica
Probiotics
Probiotica

Ondersteuning

Primaire sponsor: Heliomare Rehabiliation Wijk aan Zee
Reade Center for Rehabilitation and Rheumatology Amsterdam
Overige ondersteuning: Heliomare Rehabiliation Wijk aan Zee
Winclove Probiotics B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Confirmed diagnosis of SCI

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

- Age between 18-75 years

- Requiring treatment with antibiotics

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2016
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-04-2016
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	NL5687
NTR-old	NTR5831
Ander register	: ABR57438

Resultaten