Probiotics in the prevention of traveller's diarrhoea.

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A relative reduction of 50% in the occurence of traveller's diarrhoea.

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

Samenvatting

ID

NL-OMON23250

Bron
NTR

Verkorte titel
N/A

Aandoening

Traveller's diarrhoea, TD, traveller's diarrhea, probiotics, double blind RCT, lactobacillus, bifidobacterium

Ondersteuning

Primaire sponsor: AMC Tropencentrum.
Overige ondersteuning: The interventions is supplied by Winclove Bio Industries B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Consistency of stools according to Bristol scale;
2. Frequency of stools.

Toelichting onderzoek

Achtergrond van het onderzoek

Traveller's diarrhoea (TD) is a common health complaint affecting healthy travellers. With an incidence rate of 20-50% it has been estimated that the illness affect at least 11 million people annually. Because of the widely varying causes of TD, the chances developing an effective vaccine for prophylaxis are limited. Antibiotics are effective prophylaxis but are not recommended for widespread use and thus there is a need for cost-effective alternative treatments.

Probiotics, non-pathogenic micro-organisms which exert a positive health benefit to their host, have been suggested as a safe and effective method to prevent TD. In this study, Ecologic Travel ®, a multispecies probiotic product or a placebo is given to a group of 800 healthy, adult travellers to high risk areas for TD. By collecting Bristol scale scores such as type (consistency) of stools and frequency of stools, the occurence of TD is established. TD is defined as the passage of 3 or more unformed stools over 24 h.

Doel van het onderzoek

A relative reduction of 50% in the occurence of traveller's diarrhoea.

Onderzoeksproduct en/of interventie

Ecologic Travel ®, a multispecies probiotic product versus a placebo. Intervention consists of one sachet probiots in powder form containing the following strains: Bifidobacterium bifidum, Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus plantarum, Lactobacillus rhamnosus, Lactobacillus salivarius and Lactococcus lactis.(Minimal number of cells: 1*109cfu/g).

Contactpersonen

Publiek

Papaverweg 36 B
E. Dijk, van
Amsterdam 1032 KJ
The Netherlands

Wetenschappelijk

Papaverweg 36 B

E. Dijk, van
Amsterdam 1032 KJ
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Both male and female adults (+18);
2. Travelling to high risk area's for TD (Midle east, Asia, South and Central America, North Africa);
3. Duration of travelling: min. 7 days, max. 28 days;
4. People who experienced TD before;
5. All new travellers to high risk area's

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of antibiotics until two weeks before leaving;
2. Use of laxatives, acid blockers and diarrhoea inhibitors;
3. Persons who already have complaints about their stomach and/or intestines;
4. IBS/IBD and stoma patients;
5. Pregnant or breastfeeding women;
6. Patients with a serious disturbed or fragile/weak immune system (according to LCR criteria);
7. Use of probiotics two weeks before start of journey;
8. Frequent traveller's to high risk area's who never had TD complaints.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-01-2007
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-01-2007
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	NL654
NTR-old	NTR905
Ander register	: N/A
ISRCTN	ISRCTN76793515

Resultaten

Samenvatting resultaten

N/A