Probiotics in the prevention of traveller's diarrhoea.

No registrations found.

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

Summary

ID

NL-OMON23250

Source
Nationaal Trial Register

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: AMC Tropencentrum.
Source(s) of monetary or material Support: The interventions is supplied by Winclove Bio Industries B.V.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Duration of traveller's diarrhoea

Study description

Background summary

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.

Study objective

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

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-01-2007
Enrollment:	800
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-01-2007
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	NL654
NTR-old	NTR905
Other	: N/A
ISRCTN	ISRCTN76793515

Study results

Summary results

N/A