

Gebruik van probiotica om reizigersdiarree te voorkomen (NL)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28760

Source

Nationaal Trial Register

Brief title

N/A

Health condition

1. Diarrhoea;
2. travellers;
3. probiotics;
4. reizigersdiarree;
5. probiotica.

Sponsors and support

Primary sponsor: AMC, Travel Clinic, dept Tropical Medicine
Winclove Bio Industries bv

Source(s) of monetary or material Support: Dept tropical medicine
Winclove Bio Industries

Intervention

Outcome measures

Primary outcome

50% reduction of incidence of traveller's diarrhoea.

Study description

Background summary

Traveller's diarrhoea occurs in 20 to 50 % of travellers to low or middle income countries. Several areas of the world are known for the high incidence of diarrhoea in visitors. Probiotics have been suggested as a save and effective method to prevent traveller's diarrhoea. So far studies are inconclusive, in part because various probiotics have been used, not always well defined. In this prospective, placebo controlled, double blinded study a well defined, multispecies probiotic product will be used.

Study objective

Use of a well defined probiotic food supplement (Ecologic Travel) will reduce incidence of traveller's diarrhoea.

Intervention

Use of probiotic food supplement.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Adult travellers (18 years and above)
to high risk areas (north Africa, Middle East, Asia, South and Central America)
minimal 7 max 28 days travel.

Exclusion criteria

Use of antibiotics or probiotics up to 2 weeks before travelling
use of laxatives, acid blockers diarrhoea inhibitors
gastrointestinal disease, pregnancy/lactation, frequent travel to high risk area without having had diarrhoea.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2007
Enrollment:	800
Type:	Actual

Ethics review

Positive opinion

Date: 01-10-2007

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	NL1043
NTR-old	NTR1077
Other	: M 06/291
ISRCTN	ISRCTN76793515

Study results

Summary results

N/A