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Probiotics in the prevention of traveller's diarrhoea

Submission date	Recruitment status	[_] Prospectively registered
26/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/08/2021	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.winclove.nl/nieuws12.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Probiotics in the prevention of traveller's diarrhoea

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics board (Medisch Ethische Commissie of the AMC) on the 25th January 2007 (ref: MEC 06/291 # 07.17.0154).

Study design
Randomised, placebo controlled, parallel group, double blinded, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Traveller's diarrhoea, prebiotics, lactobacillus, bifidobacterium

Interventions
Ecologic Travel ®, a multispecies probiotic product versus a placebo. Intervention consists of one sachet probiotics 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 x 10^9 cfu/g).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Ecologic Travel ®

Primary outcome measure
1. Consistency of stools according to Bristol scale
2. Frequency of stools

Secondary outcome measures
Duration of traveller's diarrhoea

Overall study start date
12/01/2007

Completion date
01/11/2007

Eligibility

Key inclusion criteria
1. Both male and female adults (+18)
2. Travelling to high risk area's for Traveller's Diarrhoea (TD) (Middle East, Asia, South and Central America, North Africa)
3. Duration of travelling: min. seven days, max. 28 days
4. People who experienced TD before
5. All new travellers to high risk areas

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
800

Key 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. Irritable Bowel Syndrome (IBS)/Irritable Bowel Disease (IBD) and stoma patients
5. Pregnant or breastfeeding women
6. Patients with a serious disturbed or fragile/weak immune system (according to the Dutch National Coordination Center for Travelers' Health Advice [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

Date of first enrolment
12/01/2007

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Polikliniek tropische geneeskunde
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Centre for Tropics
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/#http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Winclove Bio Industries B.V. (The Netherlands)

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration