

# Probiotics in the prevention of traveller's diarrhoea

<b>Submission date</b> 26/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Probiotics in the prevention of traveller's diarrhoea

**Study objectives**

A relative reduction of 50% in the occurrence 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

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Traveller's diarrhoea, probiotics, 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:  $1 \times 10^9$  cfu/g).

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Ecologic Travel ®

### **Primary outcome(s)**

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

### **Key secondary outcome(s)**

Duration of traveller's diarrhoea

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**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)

### 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

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes