# 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 by

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 diaarhoea.

# **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**

Travel Clinic AMC, dept Tropical Medicine, K R Gadroen Amsterdam The Netherlands 31 20 5663330

#### **Scientific**

Travel Clinic AMC, dept Tropical Medicine, K R Gadroen Amsterdam

# **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