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A study of a food supplement, Galacto-OligoSaccaride (GOS) in reducing travellers diarrhea

Submission date
28/01/2014

Recruitment status
No longer recruiting

Registration date
11/02/2014

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Travellers diarrhea (TD) affects nearly one third of all travellers to tropical and subtropical regions. A small study with 159 participants comparing a galacto-oligosaccaride (GOS) and placebo (dummy) found that the incidence of travellers diarrhea was reduced by 39%. We want to carry out a larger study to confirm this important finding.

Who can participate?
The participants will be recruited among the clients of Reiseklinikken (Oslo Travel Clinic), and all healthy travellers above 5 years of age, who are going to travel 5-15 days in an area with a high risk of TD, may be included.

What does the study involve?
The participants are randomly allocated to either eat pastilles containing GOS or placebo from five days before departure and during the whole travel. During travel they will have to fill a diarrhea journal, indicating diarrhea, number of bowel movements, fever, pain, blood in stool and treatment during the travel. Those who still have diarrhea after returning home will be offered a free examination and follow-up at Reiseklinikken (Oslo Travel Clinic).

What are the possible benefits and risks of participating?
Participants receiving galacto-oligosaccaride (GOS) may have a reduced risk of contracting traveler's diarrhea.

Where is the study run from?
The study will be run from Reiseklinikken (Oslo Travel Clinic), Norway.

When is the study starting and how long is it expected to run for?
The study started in March 2014, and will run until 1600 participants have returned their forms, and this is expected to be by July 2014.

Who is funding the study?
Reiseklinikken-Oslo Travel Clinic (Norway) and Clasado Ltd (UK) provided study material and pastilles containing GOS or placebo free of charge.

Who is the main contact?
Gunnar Hasle
hasle@reiseklinikken.com

Contact information

Type(s)
Scientific

Contact name
Dr Gunnar Hasle

Contact details
Reiseklinikken
St Olavs plass 3
Oslo
Norway
N-0165
+47 90 89 09 64
hasle@reiseklinikken.com

Additional identifiers

Clinical Trials Information System (CTIS)
2014-000430-27

Protocol serial number
1

Study information

Scientific Title
A placebo-controlled, randomized, double blind study of a galacto-oligosaccharide in reducing travellers diarrhea

Acronym
GOS

Study objectives
Traveller's diarrhea: Definition of diarrhea (WHO) - The passage of 3 or more loose or liquid stools per day, or more frequently than is normal for the individual.

A galacto-oligosaccaride (GOS) may reduce the risk of contracting traveller's diarrhea (TD).

Ethics approval required

Old ethics approval format

Ethics approval(s)
Norwegian Ethical Committee, Regional Committees for Medical and Health Research Ethics (REK) - approval pending

Study design
Placebo-controlled randomized double blind study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Traveller's diarrhea

Interventions
Ingesting pastilles containing galacto-oligosaccaride or placebo (maltodextrin)

Pastilles containing galacto-oligosaccharide (B-GOS, Bimuno), 0.9 g per pastille, or placebo (maltodextrin), provided by Bimuno.
Dosage: Between 5-12 years one pastille per day, from 12-16 years two pastilles per day, and over 16 years three pastilles per day. Start 5 days prior to the travel, continue until the return day. The form should be returned 7 days after return home. There will be no follow up after this, except for those who still have diarrhea, which will be followed up like ordinary patients, although free, as a benefit for the participants.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
galacto-oligosaccaride

Primary outcome(s)
1. Incidence of traveller's diarrhea
2. Number of bowel movements

The incidence of diarrhea, i.e., > 3 loose stools per day, number of bowel movements will be registered by the patients every day, until one week after return. Later cases of diarrhea will unlikely have been contracted during the travel. Concerning pain we have planned a 'yes' or 'no' registration, as degree of pain poorly corresponds with the severity of TD.

Key secondary outcome(s))
1. Complications, treatment and hospitalisation.
2. Result of microbiological examination of those who still have diarrhea after return. These are to be considered as ordinary patients. Apart from the routine examinations (i.e., Salmonella,

Shigella, Yersinia and Campylobacter) we will perform an Enterotoxigenic Escherichia coli polymerase chain reaction (ETEC PCR), free for the patients. The participants will have given informed consent that the results from these tests may be used anonymously as results in the study.

Completion date
15/07/2014

Eligibility

Key inclusion criteria
1. Healthy travellers above 5 years of age travelling 5-15 days to countries with a high risk of TD
2. Who sign an informed consent to participate, or, if under 18 years have parents who can sign the consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Any intestinal disease
2. Antibiotic or probiotics before travelling

Date of first enrolment
15/03/2014

Date of final enrolment
15/07/2014

Locations

Countries of recruitment
Norway

Study participating centre
Reiseklinikken
Oslo

Norway
N-0165

Sponsor information

Organisation
Reiseklinikken - Oslo Travel Clinic (Norway)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Reiseklinikken-Oslo Travel Clinic (Norway)

Funder Name
Clasado Ltd (UK) provided study material, pastilles containing GOS or placebo free of charge

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?
Results article	results	01/09/2017	21/01/2019	Yes	No