

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

Submission date 28/01/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/02/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2019	Condition category Infections and Infestations	<input type="checkbox"/> 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-oligosaccharide (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-oligosaccharide (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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

2014-000430-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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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-oligosaccharide (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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Traveller's diarrhea

Interventions

Ingesting pastilles containing galacto-oligosaccharide 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-oligosaccharide

Primary outcome measure

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.

Secondary outcome measures

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.

Overall study start date

15/03/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

800

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)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.reiseklinikken.no>

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017	21/01/2019	Yes	No