ISRCTN96117208 https://doi.org/10.1186/ISRCTN96117208

Effects of yogurt containing probiotics on salivary Streptococcus mutans and Lactobacillus sp. counts in children

Submission date
30/12/2017

Recruitment status
No longer recruiting

Registration date
20/03/2018

Overall study status
Completed

Last Edited
13/02/2018

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Probiotics are live bacteria and yeasts promoted as having various health benefits. Fermented foods contain several probiotic bacteria that provide benefits especially on a digestive level. Previous research has analyzed the effect of probiotics in the mouth and have shown that certain probiotic microorganisms could reduce the saliva levels of the bacteria Mutans streptococci and Lactobacilli sp., which play an important role in the development of tooth cavities, but this effect has not been widely assessed for two probiotics (Lactobacillus casei and Lactobacillus acidophilus) available in some commercial yogurt brands in Colombia ('Original' Yogurt, manufactured by Alpina S.A.). Therefore, the aim of this study is to assess the effects of Lactobacillus casei and Lactobacillus acidophilus available in yogurt on the saliva levels of Mutans streptococci and Lactobacilli sp. in a population of Colombian children aged 6-12.

Who can participate?
Healthy children aged 6-12

What does the study involve?
Participants are randomly allocated into two groups. Those in group A drink 'Original' yogurt containing probiotics (Lactobacillus casei and Lactobacillus acidophilus) and group B drink 'Yogo-Yogo' ordinary yogurt without probiotics. Every child receives 150 g of the assigned yogurt after their lunch for five week days during three months. The children are encouraged to maintain their normal oral hygiene habits and continue to brush their teeth daily.

What are the possible benefits and risks of participating?
The children who take part in this study are given the benefit of drinking a beverage with many nutrients which either had probiotics or did not. There are no risks because the yogurt used is available in all supermarkets in the city of Bucaramanga (Colombia).

Where is the study run from?
The charity restaurant "Maria Reina de las Misiones" (Colombia)

When is study starting and how long is it expected to run for?
November 2013 to November 2017

Who is funding the study?
Universidad Santo Tomas (Colombia)

Who is the main contact?
Prof. Martha J. Rodriguez
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GIFODONTP42014

Study information

Scientific Title
Effects of yogurt containing probiotics on salivary Streptococcus mutans and Lactobacillus sp. counts in Colombian children aged from 6 to 12 years: a randomised controlled clinical trial

Study objectives
Lactobacillus casei and Lactobacillus acidophilus probiotics which are available in a yogurt called 'Original' distributed by Alpina S.A. reduce salivary Streptococcus mutans and Lactobacillus sp. counts in six to twelve year old Colombian children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Research Ethics Committee of the Dentistry School at the Universidad Santo Tomas in Bucaramanga (Colombia), 22/05/2014

Study design
Single-centre single-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Healthy children not being under antibiotic therapy the two previous months to the start of the intervention

Interventions

The children were randomised by block randomisation into group A (intervention arm: 'Original' probiotics yogurt containing Lactobacillus casei and Lactobacillus acidophilus) or group B (placebo control arm: 'Yogo-Yogo' ordinary yogurt without probiotics). Every participant received 150g of the assigned intake after their lunch during weekdays only, for a three month period.

Microbiological examinations were performed at baseline and at the end of the intervention period. Samples of stimulated whole saliva were collected directly into sterile sample bottles. In the laboratory, samples were vortexed for 30 seconds and serially diluted from 10-1 to 10-3. Two inoculums for each dilution were plated on selective agar, Mitis Salivarius-Bacitracin agar for Streptococcus mutans and Rogosa agar for Lactobacillus sp. The agar plates were coded and anaerobically incubated at 37°. The number of CFU were identified based on their morphology, size, and color with the help of a digital colony counter 24 hours after incubation for Rogosa agar plates and 48 hours for Mitis Salivarius-Bacitracin agar plates. Biochemical identification tests were also used for identification of microorganisms. CFU of individual species were estimated by a single trained investigator.

Intervention Type
Supplement

Primary outcome measure
Streptococcus mutans and Lactobacillus sp. Colony Forming Units (CFU) counts; microbiological examinations performed at baseline and at the end of the intervention period

Secondary outcome measures
Salivary pH measured using a calibrated digital pH-meter and buffering capacity at baseline and at the end of the intervention period

Overall study start date
01/11/2013

Completion date
24/11/2017

Eligibility

Key inclusion criteria
1. Healthy children
2. Both genders
3. Age 6-12 years old
4. Lactose tolerant

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Dry mouth or xerostomy
2. Morbid obesity
3. Antibiotic therapy

Date of first enrolment
16/07/2017

Date of final enrolment
16/08/2017

Locations

Countries of recruitment
Colombia

Study participating centre
Comedor Infantil Maria Reina de las Misiones (a charity restaurant for children)
Bucaramanga
Colombia
681002

Sponsor information

Organisation
Universidad Santo Tomás

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Sponsor type
University/education

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https://ror.org/01x628269

Funder(s)

Funder type
University/education

Funder Name
Universidad Santo Tomás

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
02/02/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Martha J. Rodriguez (marthajuro@gmail.com or marthajuro@ustabuca.edu.co).

IPD sharing plan summary
Available on request