

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/02/2018	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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