ISRCTN19137849 https://doi.org/10.1186/ISRCTN19137849

Comparing the effects of milk and soy-based drinks on tooth enamel

Submission date	Recruitment status	[_] Prospectively registered
14/03/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/05/2020	Oral Health	

Plain English summary of protocol

Background and study aims
Soy drinks are often promoted as healthy alternatives to cow's milk even though they can contain added sugar. This study will compare the mineral content of tooth enamel after consumption of cow's milk or a soy drink to investigate the effect of these drinks on teeth.

Who can participate?
Healthy staff and students of the University of Melbourne, aged 18-60 years.

What does the study involve?
Human enamel pieces cut from extracted third molar (wisdom) teeth with artificially-created subsurface lesions (early tooth decay lesions) are prepared and inserted into intra-oral palatal appliances (similar to removable partial dentures) that are worn by the participants. A 200 ml sample of soy drink or cow's milk will be consumed once per day for 15 days. The participants will be randomly assigned one drink for the intervention period, and then after one week where they will not insert the appliance will cross-over to consume the other drink. The drinks are commercially available in Australia. Enamel lesion mineral content of the enamel pieces in the worn appliances will be measured after each 15-day treatment in the laboratory after the enamel pieces are removed.

What are the possible benefits and risks of participating?
The expected benefit of the study is that it will provide important information on each type of drink's ability to encourage tooth decay. It is expected that milk is better than soy drink in helping to repair tooth decay lesions. There is very little risk for the participants as both of the beverages are safe for human use.

Where is the study run from?
University of Melbourne (Australia)

When is the study starting and how long is it expected to run for?
June 2018 to November 2018

Who is funding the study?
Department of Industry, Innovation and Science, Australian Government

Who is the main contact?
Prof. Eric Reynolds
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
University of Melbourne ID 1750501

Study information

Scientific Title
Effects of soy and bovine milk beverages on enamel mineral content in a randomized, double-blind in situ clinical study

Acronym
Beverage in situ clinical trial

Study objectives
Milk is superior to a soy beverage in remineralization of tooth enamel subsurface lesions in situ.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/04/2018, University of Melbourne Medicine and Dentistry Human Ethics Sub-Committee (University of Melbourne, VIC 3010; +61 38344 1539), ref: 1750501

Study design
Single-centre double-blind randomized cross-over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental caries (tooth decay)

Interventions
The double-blind, randomized, cross-over in situ clinical trial was conducted at the Royal Dental Hospital of Melbourne in 2018. Participants were randomly assigned to one of the two different test products and crossed over to the other test products with one week washout in between. Each participant was assigned a number and randomization was effected using a standard randomization table for the coded test products. Each participant wore the custom-made palatal appliance containing four enamel half-slabs with subsurface lesions and once per day for 15 days consumed 200 ml of test product. The product consumption involved 10 -15 sips of the beverage over 60 seconds allowing the beverage during each sip to contact the enamel slabs in their appliance. Participants kept a diary of beverage consumption times and duration. Participants maintained their normal diet and oral hygiene procedures for the duration of the study, however the intra-oral appliances were removed during eating and drinking (except for the test beverage) and normal oral hygiene procedures. When out of the mouth the appliances were stored in sealed humid containers. All subjects brushed their teeth with standard 1450 ppm fluoride toothpaste for the duration of the study. The subjects returned to the clinical site with their appliances, diary and empty tubes at the conclusion of each 15-day treatment period. Researchers and participants were blind to the treatment code. An independent staff member held the treatment code which was only released after data collection and analysis. After each treatment period each test half-slab was paired with its control half-slab and embedded, sectioned and analysed by transverse microradiography to determine mineral content as described previously by Cochrane et al. (2012).

Intervention Type
Supplement

Primary outcome(s)
Integrated mineral gain/loss, ΔZd-ΔZr. At the end of each treatment period each test half-slab will be paired with its control half-slab and embedded, sectioned and analysed by transverse microradiography to determine mineral content as described previously (Cochrane et al. 2012). Lesion parameters, lesion depth (LD) and integrated mineral loss (ΔZ) will be determined and the ΔZ value for the control demineralized lesion will be designated ΔZd and that for the treated lesion will be designated ΔZr. These values will then be used to calculate total mineral loss or gain ΔZd-ΔZr and percentage mineral change (%R) as (ΔZd-ΔZr/ΔZd) x 100.

Key secondary outcome(s))
Lesion depth (LDd-LDr). At the end of each treatment period each test half-slab will be paired with its control half-slab and embedded, sectioned and analysed by transverse microradiography to determine lesion depth (LD) as described previously (Cochrane et al. 2012). Lesion depth (LD) will be determined for the control demineralized lesion and will be designated LDd and that for

the treated lesion will be designated LDr. These values will then be used to calculate the change in lesion depth will be calculated as LDd-LDr.

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Healthy adults living in Melbourne, Australia, with a fluoridated (0.9 ppm F), reticulated water supply
2. Staff and students of the University of Melbourne
3. Aged 18-60 years
4. At least 22 natural teeth
5. Unstimulated whole salivary flow rate of ≥0.2 ml/min
6. Gum-stimulated whole salivary flow rate ≥1.0 ml/min

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Currently using antibiotics or medications that may affect salivary flow rates
2. History of severe oral disease

Date of first enrolment
01/07/2018

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Australia

Study participating centre
University of Melbourne
Level 6, 720 Swanston Street
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Sponsor information

Organisation
The University of Melbourne

ROR
https://ror.org/01ej9dk98

Funder(s)

Funder type
Government

Funder Name
Department of Industry, Innovation and Science, Australian Government

Alternative Name(s)
Department of Industry, Innovation and Science

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan
No personal data on the participants will be provided only enamel mineral content data of the enamel pieces worn in the appliances by each participant after treatment with the various

beverages. This information will be made available when the study is published. Prof. Eric Reynolds can be contacted for that information. The participants did provide informed consent in writing to be part of the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019	18/05/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes