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Sodium bicarbonate and gingivitis

Submission date
15/05/2017

Recruitment status
No longer recruiting

Registration date
12/09/2017

Overall study status
Completed

Last Edited
12/09/2017

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Bacterial plaque accumulation on the tooth surfaces is a well-known factor in the development of tooth decay and gum inflammation (gingivitis), therefore effective removal through daily oral hygiene practices at home is very important. However, complete plaque removal over long periods of time is not an easy task, therefore efforts have been made to supplement regular tooth cleaning with the use of agents contained in dental toothpastes. Sodium bicarbonate is one such potential substance that has been shown to reduce plaque growth. The aim of this study is to investigate the effect of a sodium bicarbonate toothpaste on plaque accumulation and gum inflammation compared to a non-sodium bicarbonate toothpaste.

Who can participate?
Healthy volunteers aged 18 – 60

What does the study involve?
All participants undergo a scale and polish to remove any existing plaque from their tooth surfaces. Between 2 to 4 weeks later, the participants are assessed and are instructed to insert a custom-made tooth guard in one corner of the mouth (Quadrant 1) every time they brush their teeth. This is repeated for 21 days in order to cause gingivitis, then for the following 2 weeks the participants are allowed to include Quadrant 1 in their toothbrushing without inserting the gum shield. Participants are randomly allocated to the test group or the control group. The test group uses sodium bicarbonate toothpaste (Corsodyl Toothpaste). The control group uses a non-sodium bicarbonate toothpaste (Aquafresh Fresh and Minty Toothpaste). The toothpastes are used until the last study visit in order to detect which is better at treating gingivitis.

What are the possible benefits and risks of participating?
All participants receive an oral health evaluation and two sessions of scaling and polishing during the study (before the start and after the end of the study). All participants have to provide blood samples. Gingivitis may cause halitosis (bad breath) and puffy and bleeding gums.

Where is the study run from?
UCL Eastman Dental Institute (UK)

When is the study starting and how long is it expected to run for?
March 2016 to September 2017

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
1. Dr Marco Orlandi
2. Prof. Francesco D'Aiuto

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15/0406

Study information

Scientific Title
Modulation of acute gingival inflammation by Na-bicarbonate: an acute inflammatory model

Study objectives
The aim of this study is to investigate the acute and reversible changes in the gingival tissue (based upon bleeding on probing) following use of a Nabicarbonate dentifrice (Corsodyl Original Toothpaste sold over the counter in the UK) or control (Aquafresh Original Toothpaste sold over the counter in the UK) using an experimental gingivitis model.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The North of Scotland REC, 19/02/2016, ref: 15-NS-0012

Study design
Parallel split-mouth double-blind prospective randomized intra-individual comparative controlled single-centre clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Gingivitis

Interventions
This is a double-blind controlled intervention clinical trial with 5 weeks follow-up aiming to evaluate and compare the acute and reversible changes in the gingival tissue, plaque accumulation and host response using a sodium bicarbonate dentifrice (or suitable placebo /control) adopting an experimental gingivitis model. Eligible healthy volunteers will be randomized to the test or control group in a 1:1 ratio. In order to avoid imbalance between the two treatment groups in terms of smoking status, gender and age restricted randomization (minimization) will be performed by the study registrar.
1. Test intervention (test toothpaste): sodium bicarbonate toothpaste (Corsodyl Toothpaste)
2. Placebo intervention (control toothpaste): non-sodium bicarbonate toothpaste (Aquafresh Fresh and Minty Toothpaste)

All participants will be scheduled for a dental prophylaxis (scale and polish) to remove any existing hard and soft deposits from the tooth surfaces. At this visit, a package for oral hygiene procedures to be carried out at home by the patient will be given and all participants will be instructed on how it should be used until the end of the gingivitis induction phase. A diary will be

provided to record home care routine. Between 2 to 4 weeks after the prophylaxis, baseline assessments will be performed and the experimental gingivitis model (5 week duration) will begin. The experimental gingivitis model consists of instructing the participants to insert a custom-made tooth guard in Quadrant 1 every time they perform a mechanical oral hygiene routine twice daily. This oral hygiene routine will be repeated for 21 days. After 3 weeks, the gingivitis induction phase will end and for the following 2 weeks the participants will be allowed to include Quadrant I in their oral hygiene procedures without inserting the gum shield. Participants will be randomised at the end of the gingivitis induction to either use test or control product during oral hygiene procedures. The test or placebo product will be used from the end of the gingivitis induction phase until the last study visit in order to detect a potential difference compared to the control in the gingivitis resolution.

Intervention Type

Primary outcome measure
Full mouth bleeding, recorded as the percentages of total surfaces (6 aspects per tooth) which revealed bleeding within 30 seconds following probing (bleeding on probing). A binary score will be assigned to each surface (1 for bleeding present, 0 for absent). Evaluated at baseline, 3 weeks and 5 weeks follow up.

Secondary outcome measures
1. Gingival response, assessed using:
1.1. Gingival Index
1.2. Probing pocket depth, gingival recession and clinical attachment levels
1.3. Laser Doppler High-resolution blood flow images of the gingival microcirculation
1.4. Optical Coherence Tomography (OCT) analysis of soft tissue volume changes
1.5. Microvascular imaging with Capiscope camera

2. Humoral and cellular gingival response to plaque accumulation, assayed in crevicular fluid (GCF) by proteomic analysis

3. Dental plaque, assessed using:
3.1. Clinical assessment visual indexes (modified Quigley-Heine plaque index, O'Leary index)
3.2. Instrumental (by Sopro fluorescence camera and OCT)
3.3. Microbiological supra-gingival sample collection, storage and processing for evaluation of shifts in ecology

4. Host response, assessed using:
4.1. Collection of unstimulated saliva and stimulated within a set interval, and analysis in saliva of bacterial and immune products
4.2. Plasma samples collection and analysis for host response (inflammatory/immune) and intracellular oxidative stress analysis

5. Vascular response, assessed using endothelial function of brachial artery, pulse wave velocity

6. Diet changes, assessed using a food diary

Measured at baseline (all secondary outcomes), 1 week (OCT, Laser Doppler, modified Quigley-Heine plaque index, O'Leary index, Sopro fluorescence camera), 2 weeks (OCT, Laser Doppler, modified Quigley-Heine plaque index, O'Leary index, Sopro fluorescence camera), 3 weeks (all

secondary outcomes), 4 weeks (OCT, Laser Doppler, modified Quigley-Heine plaque index, O' Leary index, Sopro fluorescence camera), 5 weeks (all secondary outcomes except food diary) follow-up.

Overall study start date
01/03/2016

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. Aged 18 – 60
2. Non-smoker
3. Absence of probing pocket depth ≥5 mm in more than 4 sites (excluding wisdom teeth)
4. No history of previous periodontitis and have at least 20 teeth including natural uncrowned maxillary incisors (excluding wisdom teeth)
5. Have voluntarily signed the informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Presence of systemic diseases (e.g., diabetes mellitus or cardiovascular, kidney, liver or lung disease)
2. Pregnant or breastfeeding
3. History of drug abuse
4. Using any medication to treat a chronic disease
5. Regular use of analgesic or antibiotics within 1 month before entering the study
6. Have untreated gross carious lesions and/or insufficient restorations
7. Have implants, orthodontic retainers, crowns/bridges or missing teeth/partial dentures in the maxillary arch
8. History of mouth breathing
9. Allergic to ingredients of study products or their ingredients, relevant to any ingredient in the test products as determined by the dental/medical professional monitoring the study
10. Concurrent participation in other clinical studies

Date of first enrolment
01/03/2016

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
UCL Eastman Dental Institute
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Sponsor information

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University College London

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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date