ISRCTN34881910 https://doi.org/10.1186/ISRCTN34881910

The effects of pomegranate mouth rinses on oral health

Submission date	Recruitment status	[_] Prospectively registered
23/09/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/09/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/09/2025	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Natural herbal mouth rinses are made of natural, plant-based ingredients that highlight body /mind health and wellness and are promoted as “alternatives” to the conventional over-the-counter cosmetic and therapeutic oral rinses. Therefore, this study was undertaken to assess the action of pomegranate bark extract on de novo plaque formation, compared to digluconate chlorhexidine.

Who can participate?
Healthy adult patients of both genders

What does the study involve?
The study will consist of mouthwashes after brushing teeth in the morning and evening (12-hour intervals). The mouthwashes will be 10 ml with one of three substances (placebo, 0.12% chlorhexidine, and 10% Punica granatum (pomegranate bark extract), which are used for for 1 minute for 3 consecutive days.

What are the possible benefits and risks of participating?
The expected benefits of the study are to prove the effectiveness of pomegranate peel extract as an aid in controlling plaque. Once this product is commercialized, it will be easily accessible to all social classes, demonstrating the importance of researching alternative and economically viable methods through phytotherapy.

The mouthwash procedure may cause some unpleasant taste sensations. This minimal risk will be reduced by adding products that improve the taste of the products, such as flavorings. Dental prophylaxis will be performed after the end of the study, after three days, to eliminate all remaining plaque. This period is well described in the scientific literature and poses no irreversible risk and does not cause damage to teeth and gums. Plaque will be controlled, as the most effective means of plaque control, toothbrushing, will not be discontinued.

Where is the study run from?
University of Fortaleza, Brazil

When is the study starting and how long is it expected to run for?
September 2011 to July 2016

Who is funding the study?
University of Fortaleza, Brazil

Who is the main contact?
Arlândia Cristina Lima Nobre de Morais, arlandia@unifor.br

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Sérgio Luís da Silva Pereira

ORCID ID
https://orcid.org/0000-0003-0309-5159

Contact details
Rua Romeu Aldigueri, 101 - Apto. 401 Torre Norte - Bairro Guararapes
Fortaleza
Brazil
60810-190
+55 (85) 3477-3259
luiss@unifor.br

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
272/2011

Study information

Scientific Title
Pomegranate in mouth rinses on de novo plaque formation: a double-blind clinical study

Study objectives
The present study aimed to assess the action of this herbal agent on de novo plaque formation, compared to digluconate chlorhexidine.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2011, Coética Unifor (Av. Washington Soares, 1321 - Edson Queiroz, Fortaleza, 60811905, Brazil; +55 (85) 3477-3000; coetica@unifor.br), ref: 11-335

Study design
Randomized double-blind crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Care home, Pharmacy, University/medical school/dental school

Study type(s)
Prevention, Safety, Efficacy

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

Health condition(s) or problem(s) studied
Prevention of supragingival biofilm accumulation on tooth surfaces in healthy subjects

Interventions
Preparation of the mouth rinses
Initially, 1ml of essential oil was diluted in 9 ml of distilled water (1:9), preparing a 10% mixture (V/V) (Pg solution). A mouth rinse containing just distilled water (DW solution) and another containing 0.12% chlorhexidine digluconate (CLX solution) were formulated too. In all groups, a very small amount of menthol (flavoring), color and conserving agent were added.

Clinical design
This study was a randomized, double-blind comparison of 3 crossover groups of dental students performed in 3 experimental phases of 3 days each, with a 1-month washout interval between them until all subjects had rinsed with each formulation. To standardize the groups, the participants were submitted to a meticulous evaluation (pre-experimental phase) to score the Plaque Index (PLI) (11) of each tooth. All teeth of each subject were polished and flossed by the examiner to eliminate dental plaque remnants. The importance of oral hygiene was strongly reinforced.
Thirty days after the initial phase, the volunteers were randomly assigned to 3 groups by random allocation using a computer-generated random table by a person not a participant in the study, and the experimental phase began. On day 0 of both experimental periods, PLI was recorded. During each 3-day experimental period, the participants were instructed to abstain from all forms of mechanical oral hygiene. A bottle containing 100 ml of mouth rinse was given to all students, and they were instructed to rinse 10 ml for 60 seconds, twice daily (in the morning and in the evening), and then expectorate it.

Intervention Type
Drug

Pharmaceutical study type(s)
Dose response

Phase
Phase II

Drug/device/biological/vaccine name(s)
0.12% chlorhexidine digluconate solution, 10% pomegranate solution

Primary outcome measure
Plaque index (PLI) on the tooth surface was measured using a fuchsine-revealing solution and a periodontal probe after 3 days of product use

Secondary outcome measures
Clinically significant adverse effects, including abscesses, mucosal ulcerations, or hypersensitivity reactions, were measured using data collected through clinical inspection and patient reports by the end of the study

Overall study start date
27/09/2011

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Dental students
2. At least 24 natural teeth
3. No signs of periodontitis
4. No caries or extensive dental restorations
5. No exposure to systemic antibiotic treatment during the past 6 months
5. Do not routinely use chemical plaque control

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
19 Years

Upper age limit
23 Years

Sex
Both

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
1. An orthodontic appliance
2. Medical disorders
3. Smokers
4. Pregnant women

Date of first enrolment
01/12/2015

Date of final enrolment
15/12/2015

Locations

Countries of recruitment
Brazil

Study participating centre
University of Fortaleza
Av. Washington Soares, 1321 - Edson Queiroz
Fortalez
Brazil
60811905

Sponsor information

Organisation
Universidade de Fortaleza

Sponsor details
Av. Washington Soares, 1321 - Bairro Edson Queiroz
Fortaleza
Brazil
60811905
+55 (85) 3477-3000
queroserunifor@unifor.br

Sponsor type
University/education

Website
https://unifor.br

ROR
https://ror.org/02ynbzc81

Funder(s)

Funder type
University/education

Funder Name
Universidade de Fortaleza

Alternative Name(s)
University of Fortaleza, UNIFOR

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Brazil

Results and Publications

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

Intention to publish date
25/10/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Sérgio Luís da Silva Pereira, luiss@unifor.br

IPD sharing plan summary
Available on request