

# The effects of pomegranate mouth rinses on oral health

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<b>Registration date</b> 24/09/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/09/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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### Contact details

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Prevention, Safety, Efficacy

## **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

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

0.12% chlorhexidine digluconate solution, 10% pomegranate solution

## **Primary outcome(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

19 years

**Upper age limit**

23 years

**Sex**

All

**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

## 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

## **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](mailto:luiss@unifor.br)

## **IPD sharing plan summary**

Available on request