HYPOCHLOROUS ACID SUBSTANTIVITY AS ANTIPLAQUE AGENT (HOCl-SAP) (HOCl-SAP)

This study has been completed.

Sponsor:
Universidad El Bosque, Bogotá

Information provided by (Responsible Party):
Gloria Inés Lafaurie, Universidad El Bosque, Bogotá

ClinicalTrials.gov Identifier:
NCT03174756

First received: May 31, 2017
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Last verified: May 2017
History: No changes posted

Purpose

Hypochlorous acid (HOCl) in a non-antibiotic antimicrobial agent used in clinical medicine. Nevertheless, its antiplaque oral effect has not been evaluated. Chlorhexidine (CHX) is the gold standard as an antiplaque agent for its high substantivity in plaque and saliva. There are no published studies evaluating the substantivity of hypochlorous acid compared to CHX. Objective: To evaluate the efficacy of mouthwashes of HOCl in substantivity evaluated by reduction of bacterial viability in saliva during 7 hours compared to CHX rinses and a placebo.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypochlorous Acid</td>
<td>Drug: Hypochlorous Acid</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Mouthwashes</td>
<td>Drug: Chlorhexidine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other: Placebo</td>
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</tbody>
</table>

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Intervention Model Description:

A double-blind randomized controlled trial with 75 participants was conducted. Participants were assigned using block randomization in five groups: HOCl 0.025% and 0.05%, CHX 0.12% and 0.2% and sterile water as placebo. Participants were instructed to use each rinse solution for 30 seconds after dental prophylaxis. Samples of saliva were taken at baseline and after 30 seconds, 1, 3.5 and 7 hours to assess substantivity establishing the bacterial viability by the fluorescence method.

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description:

The treatment codes of the study were not accessible to the investigators and to the examiner until the data were analyzed

Primary Purpose: Treatment

Official Title: EVALUATION OF THE HYPOCHLOROUS ACID SUBSTANTIVITY AS ANTI-PLAQUE AGENT. A RANDOMIZED CONTROLLED TRIAL

Resource links provided by NLM:

Drug Information available for: Chlorhexidine

U.S. FDA Resources

Further study details as provided by Gloria Inés Lafaurie, Universidad El Bosque, Bogotá:

Primary Outcome Measures:

- Substantivity [ Time Frame: Baseline, 30 Seconds, 1, 3, 5 and 7 hours ]
  Viability reduction (VR) was calculated for each saliva sample by the difference in the percentage of viable bacteria between two times.
Secondary Outcome Measures:

- Plaque Index [Time Frame: Baseline and 7 hours]
  Visible plaque was evaluated by Turesky Index 1970

Other Outcome Measures:

- Adverse effect [Time Frame: 24 hours]
  A survey was applied to each of the patients in order to record if any adverse effects occurred after the use of each of the interventions as burning and pain in the oral mucosa and was investigated by the taste of substances and sensation of dryness. An examiner evaluated the buccal, labial, lingual, pharyngeal and teeth tissues to establish changes and alterations visible to the clinical examination and the presence of candidiasis.

Enrollment: 75

Actual Study Start Date: January 15, 2015

Study Completion Date: November 30, 2016

Primary Completion Date: November 15, 2016 (Final data collection date for primary outcome measure)

<table>
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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
</table>
| Experimental: HOCl 0.025% 15 ml of Hypochlorous acid mouthwash at 0.025% | Drug: Hypochlorous Acid  
Mouthwashes of antiplaque agents  
Other Names:  
HClO  
Hypochlorous Acids |
| Experimental: HOCl 0.05% 15 ml of Hypochlorous acid mouthwash at 0.05% | Drug: Hypochlorous Acid  
Mouthwashes of antiplaque agents  
Other Names:  
HClO  
Hypochlorous Acids |
Active Comparator: CHX 0.2%
15 ml of chlorhexidine mouthwash at 0.2%

Drug: Chlorhexidine
A disinfectant and topical anti-infective agent used also as mouthwash to prevent oral plaque.
Other Name: CHX

Active Comparator: CHX 0.025%
15 ml of chlorhexidine at mouthwash 0.025%

Drug: Chlorhexidine
A disinfectant and topical anti-infective agent used also as mouthwash to prevent oral plaque.
Other Name: CHX

Placebo Comparator: Placebo
15 ml of Sterile water

Other: Placebo
Sterile water as placebo
Other Name: Placebos

**Detailed Description:**
Materials and Methods: A randomized, double-blind clinical trial with 75 participants was conducted. Participants were randomly assigned using block randomization in five groups: HOCl 0.025% and 0.05%, CHX 0.12 and 0.2% and sterile water as placebo. Participants were instructed to use each rinse with 10 ml of each solution for 30 seconds after dental prophylaxis. Samples of saliva were taken at baseline and after 30 seconds, 1, 3.5 and 7 hours to assess substantivity establishing the bacterial viability by the fluorescence method with the SYTO 9/propidium iodide dual staining. All participants were assessed with the Turesky visible plaque index at baseline and at 7 hours and adverse events were assessed. The effect of each rinse on bacterial viability over time was evaluated by repeated measures ANOVA, adjusted to time, treatment and time-treatment interaction. The difference in plaque index between groups at 7 hours was analyzed by one-way ANOVA.

**Eligibility**

Ages Eligible for Study: 18 Years to 25 Years (Adult)
Sexes Eligible for Study: Male
Accepts Healthy Volunteers: Yes

**Criteria**

**Inclusion Criteria:**
- Dentate young men with minimum 22 teeth were considered eligible for the study. Participants should have good dental and gingival status (DMFT index ≤ 3, median of Loe Bunge gingival index ≤ 1) and detectable levels of dental plaque at 7 hours of brushing during the selection process.

**Exclusion Criteria:**
- Exclusion criteria included smoking, orthodontic, orthopedic or rehabilitation treatment, cavitated carious lesions and consumption of systemic antimicrobials or anti-inflammatory drugs in the last 6 months.
Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT03174756

Locations

Colombia

Gloria Ines Lafaurie
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Sponsors and Collaborators
Universidad El Bosque, Bogotá

Investigators

Principal Investigator: Gloria Ines Lafaurie, MS El Bosque University

More Information

Publications:

Responsible Party:
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ClinicalTrials.gov Identifier: NCT03174756

Other Study ID Numbers: Ubosque

Study First Received: May 31, 2017

Last Updated: May 31, 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Plan Description: No requerid

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Product Manufactured in and Exported from the U.S.: No

Keywords provided by Gloria Inés Lafaurie, Universidad El Bosque, Bogotá:

Hypochlorous Acid
Chlorhexidine
Antiplaque agents
Substantivity

Additional relevant MeSH terms:

Chlorhexidine Anti-Infective Agents
Chlorhexidine gluconate Disinfectants
Anti-Infective Agents, Local Dermatologic Agents

ClinicalTrials.gov processed this record on August 18, 2017