

Chlorhexidine mouthwash for the prevention of alveolar osteitis after oral surgery

Submission date 13/08/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/08/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Alveolar osteitis (AO) is the most common complication of tooth removal. It occurs when a blood clot fails to develop in the tooth socket, or if the blood clot becomes dislodged or disappears. The empty socket causes severe pain, headaches, fever, and paresthesia (pins and needles). Today, treatments are focused on managing the symptoms and these are not very effective, highlighting the importance of preventing the development of AO. The aim of this study is to assess the effectiveness of chlorhexidine mouthwash after tooth extraction in patients who are at risk of developing AO (previous surgical site infection, traumatic extraction, and tobacco smoking).

Who can participate?

Adults who have undergone tooth extractions and are at risk of developing AO

What does the study involve?

After the tooth extraction, participants are randomly allocated to use either chlorhexidine mouthwash or sterile water for 30 seconds, twice daily for 7 days, starting 24 hours after extraction. After 7 days participants are followed-up to check whether they have developed AO.

What are the possible benefits and risks of participating?

Chlorhexidine mouthwash may reduce the chance of developing AO. The only risk is hypersensitivity (allergic reaction) to chlorhexidine.

Where is the study run from?

Valdivia and Panguipulli, Región de Los Ríos, Chile

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

June 2012 to December 2015

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Chlorhexidine 0.12% mouthwash for the prevention of alveolar osteitis after oral surgery: a double-blind randomized clinical trial

Acronym

ChAOP (Chlorhexidine for Alveolar Osteitis Prevention)

Study objectives

Chlorhexidine 0.12% mouthwash is better than placebo at preventing alveolar osteitis after oral surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethic Committee of Health Community Service of Valdivia, Chile, 22/03/2013, ORD.: N° 073

Study design

Prospective stratified parallel randomized double-blind placebo-controlled clinical trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Alveolar osteitis (dry socket)

Interventions

Treatment: consisted of a mouthwash with 15 mL chlorhexidine 0.12% (Oralgene® Mouthwash 0.12%, Maver, Chile) for 30 seconds, twice daily for 7 days, starting 24 hours after extraction.

Placebo: Sterile water, with the same indications for use as chlorhexidine.

Chlorhexidine and placebo were stored in similar brown plastic bottles, and instructions were given orally and in writing to each participant.

Patients were randomly allocated to the Chlorhexidine or Placebo group, matched by risk factors, and seven groups were formed with the following possible combinations: smoker, previous infection, traumatic extraction, smoker + previous infection, smoker + traumatic extraction, previous infection + traumatic extraction, previous infection, traumatic extraction. To avoid the risk of having more patients in a group, we stored black envelopes in a box containing a paper with the letter C for chlorhexidine or P for placebo (half of each). For each patient who was assigned to a group, the subsequent patient who arrived with the same risk factors was matched to the opposite group, and the respective envelope was discarded (to ensure homogeneity of groups).

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Chlorhexidine 0.12% mouthwash

Primary outcome(s)

Positive diagnosis of alveolar osteitis was identified in patients with the following two characteristics (both variables must be present):

1. Increasing postoperative pain intensity for 4 days within and around the socket: We asked as a dichotomous variable: yes or no. (AO presents with severe pain, therefore, this variable is easily detectable)
2. Total or partial breakdown of the blood clot in the socket with or without bone exposure: like pain, this variable is easy detectable by clinical examination, the clot should completely cover the socket for proper healing

The primary outcome was measured seven days after dental surgery

Key secondary outcome(s)

N/A

Completion date

27/12/2015

Eligibility

Key inclusion criteria

Patients with clinical indications for tooth extraction, and who presented at least one of the following risk factors for developing alveolar osteitis:

1. Tobacco smoker (consumption of ≥ 5 cigarettes 24 hrs before extraction)
2. Previous surgical site infection (clinical diagnosis of chronic periodontitis, acute periodontal conditions, apical periodontitis, pericoronitis, fungal infections, or dental pulp gangrene)
3. Traumatic extraction (lifting a flap, use of elevators for > 4 min, and/or rotary instruments)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients requiring extraction in the operating theater
2. Patients living in rural areas who manifested difficulty in returning for follow-up
3. Patients allergic to chlorhexidine
4. Patients under antimicrobial therapy, antibiotic prophylaxis, or antibiotics therapy after extraction

Date of first enrolment

01/04/2013

Date of final enrolment

27/12/2015

Locations

Countries of recruitment

Chile

Study participating centre

Dental Emergency Service " Dr Jorge Sabat Gozalo"

2500, Picarte Street

Valdivia

Chile

5090000

Study participating centre
Coñaripe Health Community Center
Las Tepas S/N
Panguipulli, Valdivia
Chile
5210000

Sponsor information

Organisation

Universidad Austral de Chile

ROR

<https://ror.org/029ycp228>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018	22/01/2019	Yes	No