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Chlorhexidine mouthwash for the prevention of alveolar osteitis after oral surgery

Submission date
13/08/2016

Recruitment status
No longer recruiting

Registration date
16/08/2016

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Dr Diego Halabi
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.: Nº 073

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
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 measure
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

Secondary outcome measures
N/A

Overall study start date
01/06/2012

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

Age group
Adult

Sex
Both

Target number of participants
744

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 Comunity Center
Las Tepas S/N
Panguipulli, Valdivia
Chile
5210000

Sponsor information

Organisation
Universidad Austral de Chile

Sponsor details
Campus Isla Teja S/N
Valdivia
Chile
5090000

Sponsor type
University/education

Website
http://www.uach.cl

ROR
https://ror.org/029ycp228

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We are preparing the manuscript for publication before this year ends (2016)

Intention to publish date
27/12/2016

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