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Efficacy of chlorhexidine in the first week after an oral biopsy

Submission date
03/04/2017

Recruitment status
No longer recruiting

Registration date
05/05/2017

Overall study status
Completed

Last Edited
09/04/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An oral biopsy (where a piece of tissue is removed in order to be analysed) may be done for patients with oral lesions (wounds or cuts) in order to figure out the cause of their lesions. This is can help diagnose different oral diseases. Oral biopsies are very common and are safe procedures. They usually consist of a small piece of the tongue, mouth or gum being removed for further analysis. They are usually quite painless procedures but they do require some healing time. Certain types of mouth wash with particular ingredients such as chlorhexidine (a disinfectant and antiseptic that reduces bacteria) could help participants heal faster, prevent pain and improve quality of life after the procedure. The aim of this study is to examine if using a chlorhexidine mouth-rinse after an oral biopsy could help patients heal faster.

Who can participate?
Adults aged 18 and older who require an oral biopsy for their history of oral lesions.

What does the study involve?
Participants undergo the standard oral biopsy procedure. They are then randomly allocated to one of three groups. Those in the first group are given a 0.12% clorhexidine mouth-rinse to take twice daily for six days (starting one day after the procedure). Those in the second group are given a 0.20% chlorhexidine mouth-rinse to take twice daily for six days (starting one day after the procedure). Those in the third group receive no treatment after their oral biopsy. Participants are followed up one week after the procedure to see how well they have healed, and to assess their pain levels and quality of life.

What are the possible benefits and risks of participating?
Participants may benefit from a quicker healing time after the oral biopsy. There are no notable risks with participating but participants are reminded to read the information sheets given by the medication.

Where is the study run from?
University of Turin (Italy)

When is the study starting and how long is it expected to run for?
April 2017 to November 2017

Who is funding the study?
Investigator initiated and funded (Italy)

Who is the main contact?
Dr Paolo G. Arduino
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DSarduino13

Study information

Scientific Title
Clinical evaluation of the effect of two different chlorhexidine formulations in mouth-rinses on the immediate postoperative period for oral mucosal biopsies: A randomized, placebo-controlled trial

Study objectives
The aim of this study is to evaluate the difference between of two different chlorhexidine formulations (012% vs 0.20%) in mouth-rinses on the immediate postoperative period for oral mucosal biopsies, and also comparing those results with patients who do not take any topical medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
A.O.U. Città della Salute e della Scienza di Torino, 07/12/2016, pots. n° 019198

Study design
Three armed randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients who need to perform an oral biopsy due to different oral conditions.

Interventions
After participants undergo the standard care for histological determination of oral lesions (oral biopsy), they are then randomly allocated to one of three groups. Allocation to the groups is performed using sequentially numbered randomization table. RANCODE (version 3.6) is used to generate the randomization sequence.

Group 1: Participants in this group are given 0.12% chlorhexidine mouth-rinse to take twice daily (10 mL) for six days to start the day after the oral biopsy.
Group 2: Participants in this group are given 0.20% chlorhexidine mouth-rinse to take twice daily (10 mL) for six days to start the day after the oral biopsy.
Group 3 (Control): Participants are given no treatment to take after the oral biopsy.

At the day of suture removal (after one week) participants are followed up for reported pain, quality of life, tissue healing are documented. The same surgeon who performed the oral biopsy conducts the follow up.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Chlorhexidine

Primary outcome(s)
1. Quality of life is detailed by the patients using the Italian version of the oral health related quality of life questionnaire measured by the Oral Health Impact Profile-14 (OHIP-14) at day six
2. Post-operative pain is detailed by the patients using a Visual Analogue Scale (VAS) at baseline, day one, three, and six

Key secondary outcome(s))
1. Early post-operative complications are detailed during the clinical evaluation at day seven
2. Healing of biopsy site is measured during the clinical evaluation at day seven

Completion date

01/11/2017

Eligibility

Key inclusion criteria
1. Consecutive caucasian patients, attending the Oral Medicine Section of the Department of Surgical Sciences, Turin Hospital
2. Patients are those normally referred for histological determination of oral lesions
3. Adults aged 18 and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
354

Key exclusion criteria
1. Clinically significant medical history (e.g. systemic infective disease, heart and vascular disease, liver disease, haematological disease, deficiency of the coagulation, diabetes and neoplastic disease)
2. Immunosuppressed or immunocompromised or those who received radiotherapy to the head and neck area
3. Already under antibiotic treatment for any other reasons or treated or under treatment with intravenous amino-bisphosphonates
4. Pregnant or lactating females; patients with incapacity to understand verbal and written instructions

Date of first enrolment
01/05/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Italy

Study participating centre
University of Turin
CIR Dental School
Via Nizza 230
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10100

Sponsor information

Organisation
University of Turin

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Industry

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Paolo G. Arduino at paologiacomo.arduino@unito.it

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/03/2020	09/04/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes