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Can an extract of a patient's own blood prevent loss of tissue in the tooth socket after wisdom tooth extraction?

Submission date
29/12/2019

Recruitment status
No longer recruiting

Registration date
22/04/2020

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
When a tooth is extracted, there are changes to the shape, and sometimes loss, of the bone and other tissues around the socket. Blood contains substances that encourage tissue growth and healing. This study aims to investigate whether placing a concentrated extract of the patient's own blood in the tooth socket after the tooth has been pulled is more effective at preventing bone loss than the usual procedure, which is to allow blood to clot in the socket.

Who can participate?
People who need a wisdom tooth extracted on both sides of their mouth.

What does the study involve?
Before the dental treatment, blood was taken from the patient to prepare the extract. The teeth were extracted as usual, but in one randomly-allocated side of the mouth the extract was placed in the socket and at the other side, a blood clot was allowed to form as usual. A stitch was used to stabilise the clot and extract. The stitch was removed 7 days after surgery.

What are the possible benefits and risks of participating?
Participants will receive tooth extraction and X-rays free of charge. Tooth extraction can be painful and the wound can get infected in a small proportion of people. There might also be pain and bruising associated with the procedure to take blood.

Where is the study run from?
Austral University of Chile

When is the study starting and how long is it expected to run for?
December 2018 to October 2019

Who is funding the study?
Austral University of Chile

Who is the main contact?
Dr Pedro Aravena, paravenat@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Pedro Aravena

ORCID ID
http://orcid.org/0000-0003-1230-4573

Contact details
1649 Rudloff St
Valdivia
Chile
5110434
+56 632221205
paravenat@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Tridimensional alveolar ridge preservation after exodontia with leukocyte- and platelet-rich fibrin (L-PRF): A split-mouth randomized clinical trial

Study objectives
The use of leukocyte- and platelet-rich fibrin (L-PRF) is more effective compared to blood clot in the 3-dimensional preservation of the measured alveolar ridge in patients undergoing upper third molar extraction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/03/2019, Comité Ético Científico Servixio de Salud Valdivia [Scientific Ethics Committee of the Health Service of Valdivia], (Via Perez Rosales 560, Edificio Prales, Oficina 307, Piso 3, Valdivia, Chile; +56 632281784; comiteeticasecretaria@gmail.com), ref: 079/2019

Study design
Split-mouth randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Please see additional files for informed consent form in Spanish.

Health condition(s) or problem(s) studied
Preservation of structure after upper third molar extraction

Interventions
The randomization of the side of the jaw (right tooth #18 and left tooth #28) that received the L-PRF and the blood clot was determined by a researcher using the "RANDBETWEEN" function of Microsoft Excel(TM) v.15.24.2016 (Microsoft, Sacramento. CA, USA) in a spreadsheet with a random number table with two columns (Column #1 alveolus tooth #18 or #28; column #2 use of L-PRF or blood clot) assigning the type of intervention to be applied in each alveolus.
An oral surgeon with more than 10 years of experience performed the extraction of third maxillary molars. The participants were prepared with a sterile perforated field cloth of 10 cm x 10 cm isolating exclusively the mouth and anesthetized using an infiltrative anesthetic technique by vestibular and palatal anesthesia around tooth #18 and #28 with two tubes of Lidocaine HCl 2% and epinephrine 1:100.000 (Lignospan® Septodont, Saint-Maur-des-Fossés, France). The third molars were then extracted without a flap using atraumatic technique according to the recommendations for simple exodontia. The post-exodontic alveoli were carefully cleaned with physiological serum and the researcher in charge of the randomization indicated the alveoli and the material to be used as alveolus filling.
The preparation of the L-PRF was done according to the recommendations of Anwandter A et al. (doi: 10.1016/j.jdent.2016.06.005). Before tooth extraction, venous blood was drawn (antecubital vein) with a 21G needle to fill 4 to 8 tubes of 10 ml each (vaccutainers: Intra-Spin®, Intra-lock International Inc.®, USA). The tubes did not contain any additive or anticoagulant. They were centrifuged for 12 min at 2700 rpm (centrifuge: Process PCO2 PC-02®, Process Ltd.®, Nice, France). After spinning, L-PRF clots were collected and stored in a closed sterile box; some of them were slightly compressed into membranes (by gravitation via a glass plate, circa 5 min). In the experimental alveolus (L-PRF), 2 to 5 previously prepared L-PRF membranes were inserted, compressed with non-dentate forceps (Temmerman A. et al., 2016) and the L-PRF was stabilized in situ with a hemostatic stitch with Vicryl 4.0 (Ethicon(TM), Johnson & Johnson, New

Jersey, New York, USA) without attempting to close the wound. In the control alveolus (blood clot) a similar haemostatic stitch only was performed on the opposite side to stabilize the clot. The patients were not aware of the type of filling used in both alveoli. The sutures were removed 7 days after the extraction.

Intervention Type
Procedure/Surgery

Primary outcome measure
Volume in mm3 of alveolar wound calculated from 3-dimensional images of plaster models obtained on both sides of the extracted third maxillary molars 7 days and 3 months after the extraction

Secondary outcome measures
1. Mesiodistal dimension of alveolar wound, defined as the limit between keratinized gum (healthy tissue) and the presence of fibrin or blood clot, measured by a second investigator using a North Carolina periodontal probe (Hu-FriedyTM. Hu-Friedy Co. Frankfurt, Germany) at 7 days and 3 months post-extraction
2. Vestibulopalatine dimension of alveolar wound, defined as the limit between keratinized gum (healthy tissue) and the presence of fibrin or blood clot, measured by a second investigator using a North Carolina periodontal probe (Hu-FriedyTM. Hu-Friedy Co. Frankfurt, Germany) at 7 days and 3 months post-extraction

Overall study start date
01/12/2018

Completion date
15/10/2019

Eligibility

Key inclusion criteria
1. Men or women aged over 18 years
2. Indications for extraction of upper third molars for orthodontic treatment or difficult hygiene control at the Dental Clinic Center of the Universidad Austral de Chile (Valdivia, southern Chile)
3. Healthy, ASA I, without systemic diseases
4. Non-smoker
5. Oral hygiene index over 80% according to WHO criteria
6. Absence of caries or teeth in a radicular state
7. Participation approved through informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The results of the Suttapreyasri & Leepong trial (2013) were considered. They showed a statistically significant horizontal maintenance in millimetres of the alveolar ridge in the PRF group (1.07±0.31 mm) compared to the control group (1.81±0.88 mm). Considering an error probability of 5%, a statistical power of 80%, the participation of 15 persons requiring bilateral tooth exodontia was considered (calculation algorithm: "power twomeans 1.81 1.07, sd1(0.88) sd2(0.31)"; STATA V.14.0. STATA CORP. Texas, USA).

Total final enrolment
16

Key exclusion criteria
1. Pregnant
2. Chronic periodontal disease
3. Chronic apical pathology
4. Receiving systemic or local pharmacological treatment in the last 3 months with antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids
5. Acute infection of the tooth to be extracted
6. Receiving treatment with anticoagulants

Date of first enrolment
01/04/2019

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Chile

Study participating centre
Dental Clinic Center of the Universidad Austral de Chile
Rudloff Street #1640
Valdivia
Chile
5110434

Sponsor information

Organisation
Universidad Austral de Chile

Sponsor details
Director of School of Dentistry of the Universidad Austral de Chile
Via Independencia 641
Valdivia
Chile
5110434
+56 63 2293900
escodonto@uach.cl

Sponsor type
University/education

Website
https://www.uach.cl/admision/principal/va1divia/odontologia

Funder(s)

Funder type
University/education

Funder Name
Universidad Austral de Chile

Results and Publications

Publication and dissemination plan
We wish to submit for review in the International Journal of Oral and Maxillofacial Surgery during January 2020.

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysedduring this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		06/03/2019	15/05/2020	No	Yes
Results article		01/03/2021	14/01/2022	Yes	No