

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

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<b>Registration date</b> 22/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/01/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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 Servicio 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

## **Study type(s)**

Treatment

## **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 (vacutainers: 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(s)**

Volume in mm<sup>3</sup> 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

## **Key secondary outcome(s)**

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-Friedy™. 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-Friedy™. Hu-Friedy Co. Frankfurt, Germany) at 7 days and 3 months post-extraction

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

## Funder(s)

**Funder type**

University/education

**Funder Name**

Universidad Austral de Chile

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during 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?
<a href="#">Results article</a>		01/03/2021	14/01/2022	Yes	No
<a href="#">Participant information sheet</a>		06/03/2019	15/05/2020	No	Yes