ISRCTN12738881 https://doi.org/10.1186/ISRCTN12738881

Can Advanced-Platelet Rich Fibrin (A-PRF), a patient blood-derived living biomaterial, prevent chronic inflammation after wisdom tooth surgery?

Submission date 09/12/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/12/2020	**Overall study status** Completed	
Last Edited 14/12/2020	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Impacted wisdom teeth are third molars at the back of the mouth that don't have enough room to emerge or develop normally. Wisdom teeth are the last adult teeth to come into the mouth (erupt). Most people have four wisdom teeth at the back of the mouth — two on the top, two on the bottom.
Surgical extraction of third molars is the most frequent dental surgery operation. The procedure often causes inflammation that affects the whole body. Studies have suggested that platelet-rich plasma (PRP) can reduce post-operative problems and improve hard and soft tissue healing. Platelet-rich fibrin (PRF) is a second generation of the platelet concentrate that prevents foreign-body responses.
This study aims to investigate the use of advanced platelet-rich fibrin (A-PRF) in reducing inflammation after wisdom tooth extraction.

Who can participate?
Otherwise healthy patients aged 18 to 65 years old, diagnosed with two impacted unilateral third molars

What does the study involve?
Participants will be randomly allocated to the test or control group.
The test group will undergo third molar removal plus the application of Advanced Platelet-Rich Fibrin (A-PRF).
The control group will receive the same procedure but with natural healing (without the use of any biomaterial).
Patients will be followed up for 1 month after surgery.

What are the possible benefits and risks of participating?
Participants will have no costs associated with surgery and laboratory tests.

Where is the study run from?
Egas Moniz Dental Clinic (Portugal)

When is the study starting and how long is it expected to run for?
November 2020 to April 2021

Who is funding the study?
1. Universidade de Santiago de Compostela (Spain)
2. Egas Moniz Institute (Portugal)

Who is the main contact?
Vanessa Machado, vmachado@egasmoniz.edu.pt

Contact information

Type(s)
Scientific

Contact name
Miss Vanessa Machado

ORCID ID
https://orcid.org/0000-0003-2503-260X

Contact details
Campus Universitário, Quinta da Granja
Caparica
Portugal
2829 - 511
+351 964805122
vmachado@egasmoniz.edu.pt

Type(s)
Scientific

Contact name
Mr João Botelho

ORCID ID
https://orcid.org/0000-0002-1019-8263

Contact details
Campus Universitário, Quinta da Granja
Caparica
Portugal
2829 - 511
964805122
jbotelho09@egasmoniz.edu.pt

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of A-PRF on preventing systemic inflammation: A pilot randomized controlled clinical trial

Acronym
WISDOM

Study objectives
Giving its anti-inflammatory properties, it could be hypothesize that A-PRF might reduce acute postoperative inflammation seen in a validated human model of acute systemic inflammation (i. e., third molar removal).
Therefore, our main hypothesis is that the use of local A-PRF after lower impacted third molars would prevent acute systemic inflammation in terms of lower peripheral levels of hs-CRP compared to natural healing after this type of procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2020, Egas Moniz Ethics Committee (Campus Universitário, Quinta da Granja, Monte de Caparica, 2829 - 511 Caparica, Portugal; +351 212946768; iuem@egasmoniz.edu.pt), ref: 903

Study design
Double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Systemic acute inflammatory response after wisdom tooth removal in otherwise healthy patients

Interventions
The test group will undergo third molar removal plus the application of Advanced Platelet-Rich Fibrin (A-PRF) on the alveolar socket.
The control group will receive the same procedure but with natural healing (without the use of any biomaterial).

Randomisation process: Participants will be randomized to test or control treatment (PRF versus no-PRF) based on computer-generated random codes. The allocation will be hidden from the surgeon by opaque envelopes to be opened right before the surgical procedure. With the exception of the placement of PRF or not, procedures will be similar for both groups.

Patients will be followed up for 1 month after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Acute inflammatory response measured by hs-C-reactive protein serum levels at 24 h after intervention

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
26/11/2020

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Two unilateral fully impacted mandibular third molars which have the same degree of surgical difficulty comparing one side with the other
2. Healthy patients without significant medical diseases or a history of bleeding problems
3. Adequate level of plaque control (plaque index (PI) <15%)
4. Non-smokers patients
5. Able to give written consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Younger than 18 years old or older than 65 years old
2. Females who were pregnant or lactating
3. Females using contraceptive methods
4. Had any reported systemic illness
5. Had chronic use of any medication within 30 d prior to the study inclusion
6. Affected by periodontitis (Tonetti, Greenwell, & Kornman, 2018)
7. Signs of pericoronitis
8. Removable upper and/or lower partial dentures
9. Had periapical and periradicular radiolucencies that were detected on X-rays

Date of first enrolment
28/12/2020

Date of final enrolment
29/01/2021

Locations

Countries of recruitment
Portugal

Study participating centre
Egas Moniz Dental Clinic
Campus Universitário
Quinta da Granja
Caparica
Portugal
2829 - 511

Sponsor information

Organisation
University of Santiago de Compostela

Sponsor details

Praza do Obradoiro, 0
Santiago de Compostela
Coruña
Spain
15705
+34 881 81 10 00
yagoleira@gmail.com

Sponsor type
University/education

Website
https://www.usc.gal/gl

ROR
https://ror.org/030eybx10

Organisation
Instituto Superior de Ciências da Saúde Egas Moniz

Sponsor details
Campus Universitário
Quinta da Granja
Caparica
Portugal
2829 - 511
+351 964805122
iuem@egasmoniz.edu.pt

Sponsor type
University/education

Website
https://www.egasmoniz.com.pt

ROR
https://ror.org/01prbq409

Funder(s)

Funder type
University/education

Funder Name
University of Santiago de Compostela

Funder Name
Instituto Superior de Ciências da Saúde Egas Moniz

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The Egas Moniz University repository named Repositório Egas Moniz (http://comum.rcaap.pt/handle/10400.26/4758).
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Type of data: Excel
When the data will become available and for how long: After completion of the research investigation (April 2021), the data will be made available for a maximum period of 3 years. After that time, the data will be removed.
By what access criteria data will be shared including with whom, for what types of analyses: The data will be shared with researchers who request access to the data by email. All requests will be evaluated together with the ethics committee Egas Moniz, and after their approval they will be made available.
By what mechanism, whether consent from participants was obtained, comments on data anonymisation, any ethical or legal restrictions, any other comments: Patient data will be anonymized.

IPD sharing plan summary
Available on request