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Autologous platelet-derived product for palatal wound healing after plastic surgery in comparison with standard surgical gelatin sponges in order to improve post-surgery experience

Submission date
29/01/2020

Recruitment status
No longer recruiting

Registration date
12/02/2020

Overall study status
Completed

Last Edited
31/01/2020

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gingival recession, also known as receding gums, is the exposure of the roots of the teeth caused by a loss of gum tissue and/or retraction of the gingival margin from the crown of the teeth. Treatment involves surgical procedures promoting root recovery. A widely accepted technique is the connective tissue graft (CTG) procedure. The tissue graft is often taken from the palate (roof of the mouth), frequently between the canine and first upper molar. There are often difficulties with wound healing, causing longer and more uncomfortable post-surgical experiences for the patients. Recently, leukocyte-platelet-rich fibrin (L-PRF) has been used to promote tissue regeneration. Consequently, patients experience less pain and better quality of life. Therefore, the aim of this study is to confirm these expected better characteristics on the palatal wound of CTG harvest procedures.

Who can participate?
Patients aged 18 to 45 years of age undergoing CTG harvest procedures

What does the study involve?
Participants undergo a CTG harvest procedure and are randomly allocated to either A-PRF application on the palatal wound or a standard surgical absorbable sponge. Pain is assessed using for the following 30 days after surgery.

What are the possible benefits and risks of participating?
The benefits of participating are the treatment of gingival recession using a standard or an innovative technique, both extremely safe. The only risk is during blood collection, although it is always performed by a trained and experienced nurse., patients may experience nausea and faint.

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?
September 2019 to September 2020

Who is funding the study?
Egas Moniz University (Portugal)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EM02001

Study information

Scientific Title
Clinical assessment of A-PRF application on the healing process of palatal wound after connective tissue graft harvest: a randomized clinical trial

Acronym
APRFHeal

Study objectives
A-PRF provides improves the healing process of palatal wounds and better post-surgical pain experience

Ethics approval required
Old ethics approval format

Ethics approval(s)
Egas Moniz Ethics Committee (Campus Universitário, Quinta da Granja, Monte de Caparica, 2829 - 511 Caparica, Portugal; Tel: +351 (0)212 946 767, Rectory Room; Email: mmarnoto@egasmoniz.edu.pt), Process number 819/2020

Study design
Single-centre triple-blinded randomized clinical 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Palatal wound after connective tissue graft harvest

Interventions
Patients were randomly assigned in a 1:1 ratio to the PRF group or control group. A random allocation sequence was performed by using a randomization program (http://www. randomizer. org). Although the surgeon and the clinical examiner are blinded to the allocation, to avoid differences in the evaluation of parameters. Since all patients underwent single-incision technique, the clinical appearance was not misleading for the clinician who evaluated the parameters.

All interventions are performed under strict sterile conditions and local anesthesia (articaine 72 mg + epinephrine 0.009 mg / 1.8 mL). A free gingival graft with about 1.5 mm thickness was removed from the palatal area from first premolar to first molar. All surgeries were supervised by the same periodontist (RA). The treatment at the test site was performed as follows:
1. Preparation of A-PRF: It was performed a standard venipuncture (median basilica vein, median

cubital vein, median cephalic vein). Ten mL of blood was drawn into a tube without anticoagulant. A-PRF is prepared by centrifuged according to the manufacturer instructions at 1,500 rpm for 8 minutes. After centrifugation, A-PRF clot from was removed from the tube and separated from the red element phase at the base with pliers. Then, A-PRF was delicately squeezed between a sterile metal plate and a metal box (gravity, no loading)
2. Palatal wound, as a result of free gingival graft harvesting, was occupied by two A-PRF clot membrane after careful positioning, and criss-cross sutures were done to hold it in position

For the control group, the surgical wound as a result of the graft collecting was filled with lyophilized hydrolyzed collagen sponge (TechnewTM, Rio de Janeiro, Brazil)

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain assessed using the Visual Analogue Scale at baseline and for the following 30 days after surgery

Secondary outcome measures
1. Edema visually measured at 7, 14 and 30 days after surgery
2. Analgesic consumption measured using a personal diary at baseline and for the following 30 days after surgery
3. Healing process measured using early healing index at 7, 14 and 30 days after surgery.
4. Connective tissue graft volume and PRF volumes measured using a periodontal probe during surgery

Overall study start date
20/09/2019

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Patients ranging from 18 to 45 years of age
2. Need connective tissue for tunnel operation or coronally flap operation
3. Non-smoking
4. Good oral hygiene
5. No gag reflex
6. No periodontal surgery before at operation site

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52 (26 per group: 26 with A-PRF and 26 with standard absorbable sponge)

Key exclusion criteria
1. Systemic disorders (immunologic diseases, uncontrolled diabetes mellitus, ongoing chemotherapy or radiotherapy)
2. Pregnancy/lactation/menstruation
3. Chronic use of anti-inflammatory or analgesic
4. Inability or unwillingness to provide informed consent

Date of first enrolment
03/02/2020

Date of final enrolment
30/05/2020

Locations

Countries of recruitment
Portugal

Study participating centre
Egas Moniz Dental Clinic
Campus Universitário, Quinta da Granja
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Sponsor information

Organisation
Egas Moniz - Cooperativa de Ensino Superior

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Sponsor type
University/education

Website
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Funder(s)

Funder type
University/education

Funder Name
Egas Moniz University

Results and Publications

Publication and dissemination plan
Both study protocol and statistical plan will not be available because they are written in Portuguese. The researchers plan to publish the results in peer-review journals.

Intention to publish date
01/07/2020

Individual participant data (IPD) sharing plan
All data will be anonymised, with codification preventing identification of the participants. All patients will provide consent. Data will be freely available, with access request needed before shared. Database will be uploaded after trial completion in Zenodo, including age, sex, VAS scores for each day, analgesic consumption, graft and PRF volumes.

IPD sharing plan summary
Stored in repository