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Blood plasma mixed with plaster as a bone substitute placed at the site where the third molar was extracted

Submission date
06/02/2021

Recruitment status
No longer recruiting

Registration date
11/02/2021

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Bone grafting is a technique that is required when a patient does not have a sufficient amount of healthy natural bones in his or her mouth that are capable of supporting dental implants.
A bone graft is a surgical procedure to repair, or rebuild, bones through the transplantation of bone tissue. By transplanting healthy bone tissue we can recreate bone and supporting tissues that are missing.
Calcium sulfate (CaSO4, Plaster París) is biocompatible, does not induce inflammatory reactions, can repair, and heal the bone, it is easy to obtain, osteoconductive, economical, abundant in nature and sterilizable. It is absorbed by dissolution in 8 weeks, depending on the volume and site of implantation.
Plasma Rich in Growth Factors (PRGF) is obtained from the patient's blood, eliminating the possibility of disease transmission, as well as having a convenient obtainment cost . The advantages of PRGF use include there being less post-operative inflammation, faster soft and hard tissue healing (obtaining a better bone quality) and minimizing the risk of infections.
The aim of this study was to evaluate the mixture of Calcium Sulfate and Plasma Rich in Growth Factors (CaSO4+PRGF) as a bone-graft-substitute.

Who can participate?
Patients aged between 18 and 25 years old, male, or female, with two mandibular third molars in a vertical position, according to Winter's classification without active infection and who attended the Oral Surgery Clinic in the Autonomous University of Yucatan.

What does the study involve?
Participants will be randomly allocated to receive either bone graft using CaSO4+PRGF or traditional treatment.

What are the possible benefits and risks of participating?
The combination and placement of CaSO4+PRGF graft in alveoli showed higher Radio-opacity /Bone Reegeneration velocity and soft tissue scarring, as well as less post-operative pain and faster recovery. It is therefore considered to be a suitable material for Bone Regeneration, that

also proves to be easy to acquire and low-cost.
There were no risks to participants other than any post-operative risks.

Where is the study run from?
Facultad de Odontología, Universidad Autónoma of Yucatán (Dental school, Autonomous University of Yucatán, Mexico)

When is the study starting and how long is it expected to run for?
June 2015 to June 2016

Who is funding the study?
Facultad de Odontología, Universidad Autónoma of Yucatán (Dental school, Autonomous University of Yucatán, Mexico)

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
FODO-2014-007

Study information

Scientific Title
Calcium sulfate and plasma rich in growth factors enhance bone regeneration after extraction of the mandibular third molar: a proof of concept study

Study objectives
A mixture of Calcium Sulfate and Plasma Rich in Growth Factors (CaSO4+PRGF) as a bone-graft-substitute in extracted mandibular third molars (MTM) alveoli.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2015, Centro de Investigaciones Regionales Dr. Hideyo Noguchi Bioethics Committee (UADY, Calle 43 s/n, Inalámbrica, 97225 Mérida, Yuc. México; +52 999 924 5809; pruz@correo.uady.mx), ref: 0026-2015

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

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
Third molar extraction

Interventions
An analytical, prospective, experimental and longitudinal study was performed. Sample: potential patients aged between 18 and 25 years old, male or female, with two mandibular third molars (MTM) in vertical position, according to Winter's classification without active infection and who attended the Oral Surgery Clinic in the Autonomous University of Yucatan.

All procedures were performed by the same operator (PRGF preparation, surgical procedure and CaSO4 spheres) MTM were extracted, with immediate placement of CaSO4+PRGF (EG) in the right alveolus (for convenience), and the left was managed in a “traditional” manner (healing and physiological blood clot formation (CG)).

Second Mandibular Third Molars were extracted.
Control group: left alveoli was managed in a “traditional” manner healing with physiological blood clot formation.
Experimental group: immediate placement of CaSO4+PRGF (EG) in the right alveolus (for convenience).

For grafting, CaSO4 (MDC® Dental, Zapopan, Jalisco, México) spheres with a diameter of 2-2.5 mm were made, sterilized at 123°C via dry heat sterilization (LORMA M-08® Mexico City, Mexico) for 40 minutes. The patient's blood was then obtained using the BTI© Plasma Transfer Device kit (PTD®, BTI Biotechnology Institute, Vitoria-Gasteiz, Álava, Spain) and the Endoret® BTI (BTI Biotechnology Institute, Vitoria-Gasteiz, Álava, Spain) centrifuge at 2000 rpm for 8 minutes. From 9 cc of whole blood, 2cc of PRGF was obtained in a sterile stick, adding 50µL/cc of calcium chloride (PRGF activator) and CaSO4 spheres until a gummy consistency was obtained (CaSO4+PRGF).

Lower third molar extraction and graft placement: Under an asepsis and antisepsis protocol, truncular anesthesia with Dentocain of the lower dental nerve was performed. A full-thickness triangular flap was created. With a low-speed handpiece with sterilized water irrigation and 703 milling bur, osteotomy and odontosection, elevation extraction of the third molars. The CaSO4+PRGF graft was placed in the right alveolus leaving the left side with the natural clot. Both were sutured with 4-0 silk.

Immediate post-surgical periapical x-rays were carried out (Satelec X-Mind DC® X-ray equipment, Burnlea Grove, Birmingham, England). Post-operative indications and medication were given: one 20 mg capsule of Meloxicam every 12 hours for 5 days; one 10mg. Ketorolac tablet every 8 hours for 5 days; one 300 mg. Clindamycin capsule 8 hours for 5 days and Bexident Gums gel (ISDIN®, Barcelona, Cataluña, Spain) after toothbrushing (3 times a day) for one month. Sutures were removed 7 days after the procedure and photographic and periapical x-rays records were taken to assess the degree of closure and healing of the surgical site.
To measure bone regeneration radiographically (Ro/BR), a homemade grey standardized aluminium scale (GSAS) was used. Each step of the scale was numbered from 1 to 6 corresponding to a difference of 16.66%, until 100% recording the results.

Intervention Type
Procedure/Surgery

Primary outcome measure
Bone regeneration measured radiographically (Ro/BR) using immediate post-surgical periapical x-rays. Each step of the scale was numbered from 1 to 6 corresponding to a difference of 16.66%, until 100%. For the systematic evaluation of the periapical x-rays, a diagram of the alveoli was designed, dividing them into four quadrants I to IV. I and IV represent distal quadrants and II and III mesial. Each quadrant was divided into three areas A, B and C from the periphery towards the center of the alveolus.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
08/06/2015

Completion date

09/06/2016

Eligibility

Key inclusion criteria
1. 18 to 25 years old
2. Two mandibular third molars in a vertical position, according to Winter's classification without active infection

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Study for convenience. 10 patients divided in two groups of 5.

Total final enrolment
10

Key exclusion criteria
1. Pregnant
2. Neurological deficiency

Date of first enrolment
10/08/2015

Date of final enrolment
10/01/2016

Locations

Countries of recruitment
Mexico

Study participating centre
Universidad Autónoma of Yucatán (Dentistry school)
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/032p1n739

Funder(s)

Funder type
University/education

Funder Name
Universidad Autónoma de Yucatán

Alternative Name(s)
Autonomous University of Yucatan, UADY

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Mexico

Results and Publications

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

Intention to publish date
20/02/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/02/2021	30/03/2023	Yes	No