

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/03/2023	Condition category Oral Health	<input type="checkbox"/> 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 Paris) 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 Regeneration 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

There are no secondary outcome measures.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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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Costado sur parque "de la Paz"

Centro

Mérida

Mexico

97000

Sponsor information**Organisation**

Autonomous University of Yucatán

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

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