ISRCTN16849867 https://doi.org/10.1186/ISRCTN16849867

Platelet rich fibrin effects on third molar surgery

Submission date
06/03/2017

Recruitment status
No longer recruiting

Registration date
10/03/2017

Overall study status
Completed

Last Edited
26/04/2017

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Impacted mandibular third molar extraction (also known as wisdom teeth removal) is one of the most common operations in oral and maxillofacial (mouth and teeth) surgery. Wisdom teeth grow at the back of the mouth and are the last teeth that come up through the gums, usually when people are young adults. Due to a lack of space, wisdom teeth can come through the gums on an angle causing them to be impacted. This usually means they need to be removed surgically. The operation consists of a small cut into the gum, extracting (removing) the tooth and then stitching up the area where the tooth was. Usually, the wound heals within a week or two however patients can experience some pain and are at risk of developing dry socket (a dull ache in the gum or jaw and a bad smell or taste coming from the area the tooth was removed). In order to encourage healing, platelet rich fibrin (PRF) has been suggested to be used on the tooth removal area. PRF is collected from the patients' blood and is then processed to separate out the platelets in order to be placed on the site where the tooth was removed. PRF is thought to help increase healing and reduce the possibility of complications. The aim of this study is to see how well PRF helps reduce edema (swelling) and pain after impacted mandibular third molars surgery.

Who can participate?
Adults aged 17-27 who require the removal of their impacted mandibular third molar.

What does the study involve?
Participants give a small sample of blood which is then processed in order to separate out the PRF. Participants then undergo the removal of their wisdom teeth in their lower jaw. Both of the lower wisdom teeth (right and left) are removed according to the standard level of care. However, the right side tooth removal area receives PRF (placed on the area with dental forceps (tool)) and the left side tooth removal area does not receive PRF. Both tooth removal areas are stitched up. Participants receive follow up for seven days after the procedure where they are tested for pain and edema.

What are the possible benefits and risks of participating?
Participants may benefit from a shorter recovery time. There are no notable risks with participating however participants may feel some discomfort when giving the blood sample.

Where is the study run from?
Ankara University Dentistry Faculty Oral and Maxillofacial Surgery Department (Turkey)

When is the study starting and how long is it expected to run for?
June 2011 to October 2013

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mehmet Fatih Şentürk
mehmetsenturk@sdu.edu.tr

Contact information

Type(s)
Scientific

Contact name
Dr Mehmet Fatih Şentürk

Contact details
Suleyman Demirel University
Dentistry Faculty
OMFS Dept.
Çünür
Isparta
Türkiye
06500
+90 (0)536 333 0252
mehmetsenturk@sdu.edu.tr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of platelet rich fibrin on edema and pain following third molar surgery: A split mouth control study

Study objectives

The aim of this study is to evaluate the efficacy of platelet-rich fibrine (PRF) on postoperative edema and pain after impacted mandibular third molar surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Committee of the Ankara University Faculty of Dentistry, 28/11/2011, ref: 25/1

Study design
Prospective split-mouth randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files (in Turkish)

Health condition(s) or problem(s) studied
Bilateral impacted third molars

Interventions
Participants are selected based off their need for the removal of bilaterally (right-left) impacted mandibular third molars.

Prior to the procedure, participants have blood collected. After placing the collected blood in a centrifuge for 12 minutes to separate the different components, the platelet rich fibrin (PRF) is collected and prepared to be applied to the patient.

Participants then have both their left and right mandibular third molar extracted (done to the standard level of care). After extraction, participants receive PRF only to the right tooth extraction area. The left tooth extraction area does not receive anything. Both extraction sits are sutured. PRF is placed into the extraction area (tooth socket) using dental forceps.

Participants are followed up for seven days after the study. Follow up involves measurements of participants pain and edema of the extraction areas and takes place at the Ankara University Dentistry faculty Oral and Maxillofacial Surgery department. For standardisation reasons, all measurements are done by the same surgeon.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain is measured using a visual analogue scale (VAS) and Verbal rate scale (VRS) at 6 and 12 hours and 1, 2, 3 and 7 days after surgery.

Secondary outcome measures
Edema is measured using a flexible ruler at baseline, 2 and 7 days.

Overall study start date
06/06/2011

Completion date
19/10/2013

Eligibility

Key inclusion criteria
1. Healthy patients without significant medical diseases or a history of bleeding problems
2. Symmetrical impacted third molars which feature the same level of surgical difficulty that require the same surgical technique to be performed
3. The third molars in the Class I, Level B position (according to Pell &Gregory) and in the vertical positions according to Winter
4. Aged 17–27 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Pregnant and lactating women
2. Signs of pericoronitis
3. Chronic use of medications such as antihistamines, non-steroidal anti-inflammatory drugs (NSAID), steroids and antidepressants which would complicate the evaluation of their postoperative response

Date of first enrolment
03/09/2012

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
Türkiye

Study participating centre
Ankara University Dentistry Faculty Oral and Maxillofacial Surgery Department
Emniyet Mahallesi
Ankara
Türkiye
06500

Sponsor information

Organisation
Ankara University

Sponsor details
Dentistry Faculty
Oral and Maxillofacial Surgery Department
Besevler
Ankara
Türkiye
06500
+90 (0)312 296 5576
fatih.senturk84@gmail.com

Sponsor type
Hospital/treatment centre

Website
dentistry.ankara.edu.tr

ROR
https://ror.org/01wntqw50

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Uğur Gülşen (ugrgulsen@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		07/03/2017	14/03/2017	No	Yes
Results article	results	24/04/2017		Yes	No