

The effectiveness of two types of fibrin (a protein found in human blood) in decreasing pain and improving healing after tooth extraction

Submission date 28/09/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/12/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Some physiological changes may occur following tooth extraction, and the symptoms may affect the patient's quality of life. Many techniques have been developed to improve pain and soft tissue healing. The aim of this study is to compare the pain and early soft tissue healing characteristics of extraction sites treated with leukocyte-and-platelet-rich fibrin (L-PRF) and advanced platelet-rich fibrin (A-PRF).

Who can participate?

Patients aged 18–50 undergoing tooth extraction

What does the study involve?

Participants are randomly allocated into three groups to be treated with advanced platelet-rich fibrin, leukocyte platelet rich fibrin, or no additional treatment after tooth extraction. Afterwards, participants in each group are assessed for pain, number of analgesics used, and early soft tissue healing.

What are the possible benefits and risks of participating?

The treatment may accelerate soft tissue healing and decrease pain. Some participants may feel unwell or faint during or after the procedure.

Where is the study run from?

Umm Al-Qura University (Saudi Arabia)

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

October 2019 to April 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Dr Moroj Sindi
s435007101@st.uqu.edu.sa

Contact information

Type(s)
Scientific

Contact name
Dr Moroj Sindi

Contact details
Al awali
Makkah
Saudi Arabia
24372
+966 (0)555252409
s435007101@st.uqu.edu.sa

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRB 143-19

Study information

Scientific Title
The effectiveness of advanced platelet-rich fibrin in comparison with leukocyte-platelet-rich fibrin on outcome after dentoalveolar surgery

Study objectives
Advanced platelet-rich fibrin is more effective than leukocyte platelet-rich fibrin in decreasing post-extraction pain and early soft tissue healing.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 19/01/2020, Umm Al-qura University Faculty of Dentistry Institutional Review Board
(Umm Al-Qura University, Makkah, 24373, Saudi Arabia; +966 (0)125270000; irb.uqudent@uqu.edu.sa), irb: 143-19

Study design

Interventional single-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 participant information sheet

Health condition(s) or problem(s) studied

Pain and soft tissue healing after tooth extraction

Interventions

Patients are divided by stratified randomization into three groups:

Group I: 20 patients treated with advanced platelet-rich fibrin after tooth extraction

Group II: 20 patients treated with leukocyte platelet-rich fibrin after tooth extraction

Group III: 20 patients receive no additional treatment

Afterwards, patients in each group are assessed for post-extraction pain on the first and second day by VAS, the number of analgesics taken after 6, 12, 18, 24 hours, and early soft tissue healing at the first and second week by LWHI.

Follow up is weekly for 2 weeks.

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Leukocyte platelet-rich fibrin, advanced platelet-rich fibrin

Primary outcome measure

1. Pain measured using a visual analogue scale (VAS) after 1 and 2 days
2. Number of analgesics taken, recorded after 6, 12, 18 and 24 hours

3. Soft tissue healing measured using the Landry Wound Healing Index (LWHI) after 1 and 2 weeks

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

10/10/2019

Completion date

29/04/2020

Eligibility

Key inclusion criteria

1. Able to speak and communicate in Arabic and English
2. Single posterior tooth extraction
3. Aged 18–50
4. Male or female
5. Surgical or extraction site free of active infection
6. Free of significant systemic disease

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Total final enrolment

60

Key exclusion criteria

1. Patients undergoing chemotherapy and radiotherapy
2. Mentally retarded
3. Medical condition affecting wound healing such as uncontrolled diabetes mellitus
4. Pregnant women

Date of first enrolment

19/01/2020

Date of final enrolment

14/04/2020

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Saudi Arabia

Alabdeyah uqudent

Makkah

Saudi Arabia

24236

Sponsor information

Organisation

Umm al-Qura University

Sponsor details

Al Abdeyah

Mecca

Saudi Arabia

24373

+966 (0)125270000

s435007101@st.uqu.edu.sa

Sponsor type

University/education

Website

<https://uqu.edu.sa/english>

ROR

<https://ror.org/01xjqrm90>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact journal at the end of December 2020. The study protocol and informed consent form will be made available.

Intention to publish date

31/12/2020

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 Arwa Almatrafi (Aroooost17@hotmail.com). The data will be available for anyone who wishes to access the data for any analysis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/05/2021	07/12/2021	Yes	No