ISRCTN13878305 https://doi.org/10.1186/ISRCTN13878305

The influence of platelet-rich fibrin on pain, bleeding, swelling, and soft tissue healing after tooth extraction

Submission date
06/11/2020

Recruitment status
No longer recruiting

Registration date
09/11/2020

Overall study status
Completed

Last Edited
15/03/2022

Condition category
Oral Health

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

Plain English summary of protocol
Background and study aims
Platelet-rich fibrin (PRF) is a biomaterial that is prepared from the patient's own blood and can be used as a membrane for root coverage purposes after tooth extraction.
The study aimed to assess the influence of Plasma Rich Fibrin (PRF) in post-transition extraction on pain, bleeding, swelling, and soft tissue healing.

Who can participate?
Patients between 18 and 40 years of age having molar extraction.

What does the study involve?
Participants will be randomly allocated to receive either PRF or saline solution applied to the area following tooth extraction and will be followed up for 15 days.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Taibah University College of Dentistry (Saudi Arabia)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ibrahim Nourwali
ibrahim_germany@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Ibrahim Nourwali

Contact details
Taibah University
Dental college
Oral and Maxillofacial department
Madinah
Saudi Arabia
42313-5141
+966 550939364
ibrahim_germany@hotmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TUCD-REC20160204

Study information

Scientific Title
The influence of platelet-rich fibrin on post-surgical complications following the removal of impacted wisdom teeth

Study objectives
There is no effect of platelet-rich fibrin on complications following surgical removal of lower impacted wisdom teeth

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/02/2016, Taibah University College of Dentistry REC (Al Arkam Ibn Abi Al Arkam, Al-Madinah Al-Munawarah, Medina, 42313-5141, Saudi Arabia; +966 552884839; TUCDREC@taibahu.edu.sa), ref: TUC-REC20160204

Study design
Interventional 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 patient information sheet.

Health condition(s) or problem(s) studied
Pain following wisdom tooth extraction

Interventions
During all the surgical procedures, all the extractions were accomplished by elevating a full-thickness mucoperiosteal flap. Following the reflection of the mucoperiosteal flap in the conventional dento-alveolar surgery with or without PRF, the osteotomy was carried out with a 1.6 mm round bur attached to a Kavo straight surgical hand-piece, using copious irrigation. All of the teeth were completely removed.

In the study group, following the tooth extraction, the PRF was implanted into the extraction socket. In the control group, a sterile physiologic saline solution was used to wash the extraction sockets. The post-extraction sockets were closed by 3–0 polyglycolic acid non-resorbable sutures were used.

Randomization of participants into groups using sealed envelopes.

Intervention Type
Procedure/Surgery

Primary outcome measure
Measured at 1, 2 and 6 h post-operatively:
1. Pain (Visual Analogue Scale [0 to 5])
2. Bleeding ((Visual Analogue Scale [0 to 4])

Secondary outcome measures
On days 1, 2, 3, 7 and 15 post-operatively:
1. Swelling, assessed by the surgeon

Overall study start date
05/02/2016

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Presence of unilateral or bilateral premolars or molars indicated for extraction
2. American Society of Anaesthesiologists (ASA) physical status classification; ASA grade I

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Pregnant women
2. Patients allergic to penicillin
3. Patients using other medications during the typical follow-up period

Date of first enrolment
15/03/2016

Date of final enrolment
15/06/2016

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Taibah University College of Dentistry (TUCoD)
Al Arkam Ibn Abi Al Arkam
Departments of Oral and Maxillofacial Surgery
Al-Madinah Al-Munawarah
Madinah
Saudi Arabia
42313-5141

Sponsor information

Organisation
Taibah University

Sponsor details
College of Dentistry
Al Arkam Ibn Abi Al Arkam
Al-Madinah Al-Munawarah
Medina
Saudi Arabia
42313-5141
+966 14861888
TUCDREC@taibahu.edu.sa

Sponsor type
University/education

Website
https://www.taibahu.edu.sa/Pages/AR/Home.aspx

ROR
https://ror.org/01xv1nn60

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
31/12/2020

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		13/03/2021	15/03/2022	Yes	No