

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

<b>Submission date</b> 06/11/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/03/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Ibrahim Nourwali

**Contact details**

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**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

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Medina

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## 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?
<a href="#">Results article</a>		13/03/2021	15/03/2022	Yes	No