Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of Platelet-Rich Fibrin (PRF) on pain, swelling, and ecchymosis after impacted third molar surgery

Protocol summary

Study aim
Determining the effect of PRF on pain, swelling, and ecchymosis after impacted third molar surgery

Design
An open label randomized clinical trial study with parallel groups and phases 3 on 34 patients. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct
In this study open label, patients requiring surgery for impacted third molars who are referred to the Oral and Maxillofacial Surgery Clinic of Zahedan Dental School will be included.

Participants/Inclusion and exclusion criteria
In this study, patients over 18 years of age requiring surgery for impacted third molars will be included. Major exclusion criteria include coagulation disorders, allergy to lidocaine, use of psychotropic and anticoagulant drugs, pregnancy, and breastfeeding.

Intervention groups
For patients in the intervention group, following anesthesia administration via injection of the local anesthetic 2% Lidocaine, a full-thickness mucoperiosteal flap will be raised with a distal releasing incision relative to the third molar to achieve access. Following the removal of the impacted tooth and irrigation of the socket with a minimum of 30 cc of normal saline, the prepared Platelet-Rich Fibrin (PRF) derived from the patient's blood sample will be placed into the socket. The flap will subsequently be closed using simple sutures with non-absorbable 3-0 silk suture material, which will be removed one week post-surgery. In the control group, routine treatment will be performed. Identical postoperative measures will be implemented for all patients, including analgesics (Noufen/Ibuprofen as needed for pain), antibiotics (Amoxicillin 500 mg every 8 hours), and 0.2% Chlorhexidine mouthwash every 12 hours for one week.

Main outcome variables
Pain; swelling and ecchymosis

General information

Reason for update

Acronym
PRF(Platelet Rich Fibrin)

IRCT registration information
IRCT registration number: **IRCT20250428065513N1**
Registration date: **2025-11-05, 1404/08/14**
Registration timing: **prospective**

Last update: **2025-11-05, 1404/08/14**
Update count: **0**

Registration date
2025-11-05, 1404/08/14

Registrant information

Name
shirin haghighimoghaddam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3337 2151

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2026-01-20, 1404/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of Platelet-Rich Fibrin (PRF) on pain, swelling, and ecchymosis after impacted third molar surgery

Public title
Studying the effect of PRF on outcomes of impacted third molar surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient's impacted third molar may require surgery, as determined by the dentist. Aged over 18 years

Exclusion criteria:
Coagulation disorders Allergy to the anesthetic lidocaine Use of psychotropic and anticoagulant drugs Pregnancy and breastfeeding

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into intervention and control groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered (34 patients), and then in the block section, the Block randomization method will be selected. Patients will be allocated in intervention or control groups based on generated numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
An open-label randomized clinical trial study with parallel groups and phases 3 on 34 patients. Randomization will be done with the block randomization method using Random allocation software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences., Doctor Hesabi square. Khalij Fars Blvd., Zahedan., Iran.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
-

Approval date
2025-10-05, 1404/07/13

Ethics committee reference number
IR.ZAUMS.REC.1404.221

Health conditions studied

1

Description of health condition studied
Impacted third molar surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain

Timepoint
Third, seventh, and twenty-first days after surgery

Method of measurement
Visual Analogue Scale (VAS)

2

Description
Swelling

Timepoint
Before the intervention and on the third, seventh, and twenty-first days after surgery

Method of measurement
The numerical value of the swollen area on the face, measured by vertical and horizontal indicators with calipers.

3

Description
Ecchymosis

Timepoint
Third, seventh, and twenty-first days after surgery

Method of measurement
Skin discoloration caused by blood leaking from blood

vessels into the subcutaneous tissues, measured with a caliper.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For patients in the intervention group, following anesthesia administration via injection of the local anesthetic 2% Lidocaine, a full-thickness mucoperiosteal flap will be raised with a distal releasing incision relative to the third molar to achieve access. Following the removal of the impacted tooth and irrigation of the socket with a minimum of 30 cc of normal saline, the prepared Platelet-Rich Fibrin (PRF) derived from the patient's blood sample will be placed into the socket. The flap will subsequently be closed using simple sutures with non-absorbable 3-0 silk suture material, which will be removed one week post-surgery. Postoperative care will be including analgesics (Noufen/Ibuprofen as needed for pain), antibiotics (Amoxicillin 500 mg every 8 hours), and 0.2% Chlorhexidine mouthwash every 12 hours for one week.
Category
Treatment - Surgery

2

Description
Control group: In the control group, routine treatment will be performed.Postoperative care will be including analgesics (Noufen/Ibuprofen as needed for pain), antibiotics (Amoxicillin 500 mg every 8 hours), and 0.2% Chlorhexidine mouthwash every 12 hours for one week.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and Maxillofacial Surgery Clinic, Zahedan Dental School
Full name of responsible person
Dr.Mehrdad Shahraki
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Faculty of Dentistry., Azadeghan Shargh Ave., Zahedan., Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Mehrdad Shahraki
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable