Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Platelet-rich fibrin (PRF) on Post-surgical Complications of Impacted wisdom tooth surgery in adults

Protocol summary

Study aim

Study of effects of platelet-rich fibrin on post-operative complications of mandibular impacted wisdom tooth surgery in adults

Design

Two arm parallel group randomized clinical trial , intervention and control are in a same person, double blinded, on 30 patients, randomized by Balanced (permuted) block randomization

Settings and conduct

Choosing patients based on entrance criteria. Similarity of surgery hardness is asserted by the expert surgeon. Patient assessment and taking informed asset form. Getting 10 ccs vascular blood sample before each operation. PRF preparation and placement after tooth extracted by surgeon. Using a same flap, bur, suturing cord and type of suture and irrigator. Prescription of Paracetamol, Amoxicillin and CHX for one week. Assessment of pain(due to NRS table), edema, bleeding, infection or dry socket for 24 and 72 hours and 7 days after surgery. Patients are blind because of getting blood sample on each operation.

Participants/Inclusion and exclusion criteria

Adult patients with bilateral inter-bone impacted wisdom tooth would be included in the study. Patient who are pregnant, lactating or having pre-operative sign or symptom, pathology in impaction area or allergy to Penicillin, Paracetamol, chlorhexidine would be excluded.

Intervention groups

In each patient, one side of the mouth would be intervention side and the other side is control. In intervention side, PRF taken from patient's blood, would be placed in empty socket of extracted tooth and surgical flap would be sutured. In control side, surgical flap would be sutured without placement of any material.

Main outcome variables

Difference or similarity between intervention and control side

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201227049849N1**
Registration date: **2021-01-13, 1399/10/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-13, 1399/10/24**
Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Parisa Kiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

kiani-p@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-09, 1399/10/20

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Platelet-rich fibrin (PRF) on Post-surgical Complications of Impacted wisdom tooth surgery in adults

Public title

Effects of Platelet-rich-fibrin on Post-surgical Complications of Impacted wisdom tooth surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults Patients with bilateral inter-bone impacted wisdom tooth

Exclusion criteria:

Pregnancy Lactation Having pre-operative sign or symptom Existence of pathology in impaction area Allergy to Penicillin, Paracetamol, chlorhexidine

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each patient, on side of the mouth would be the intervention side and the other side would be the control side.

Randomization (investigator's opinion)

Randomized

Randomization description

For randomizing each left or right side wisdom tooth of cases in intervention or control group, at first, a randomizing list would be gotten from this website www.sealedenvelope.com/simple with Balanced (permuted) block randomization technic and based on the entrance number of each case, left or right side wisdom tooth of patients would be allocate to group A (control group) or group B (intervention group).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient's blood samples would be gotten before each operation(whether for intervention side or control side).Therefore, patients would not be aware of intervention or control side. Data analyzer would receive the data as left side and right side instead of intervention side and control side.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Science

Street address

Pezeshk Blvd, Ghotb ravandi Ave

City

Kashan

Province

Isfehan

Postal code

8715981151

Approval date

2020-12-09, 1399/09/19

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.158

Health conditions studied

1

Description of health condition studied

Platelet-rich fibrin

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

post-operative pain degree

Timepoint

First 7 days after surgery

Method of measurement

0-10 Numeric Pain Rating Scale

2

Description

post-operative edema amount

Timepoint

1,3 and 7 days after surgery

Method of measurement

The distance between tragus and mouth commissure in horizontal plane and the distance between lateral cantus and gonion in vertical plane, would be measured by a flexible band.

3

Description

post-operative bleeding amount

Timepoint

3 and 7 days after surgery

Method of measurement

Massive, uncontrollable bleeding since 2nd day of surgery would be conformed by patient.

4

Description

Post-operative infection manifestation

Timepoint

4- 7 days after surgery

Method of measurement

Assessment of pus discharge, redness and temperature increasing after the 3rd day after surgery

5

Description

Post-operative dry socket manifestation

Timepoint

4- 7 days after surgery

Method of measurement

Presence of extreme pain not being decreased by taking analgesics and empty socket without pus discharge or fever

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Placement of Platelet-rich fibrin taken from patient's blood sample in empty extracted tooth socket and suturing the flap with 3/0 silk cord

Category

Prevention

2

Description

Control group: Not placing any material in extracted tooth socket. Suturing the flap with 3/0 silk cord.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Dental School

Full name of responsible person

Amirsalar Sayedyahossein

Street address

Pezeshk Blvd, Ghotb ravandi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan 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?

No

Title of funding source

Kashan University of Medical Science

Proportion provided by this source

4

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

Kashan University of Medical Sciences

Full name of responsible person

امیرسالار سیدیاحسین

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Parisa Kiani

Position
دانشجو

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available