Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of injectable platelet-rich fibrin in post-operative healing after tooth crown lengthening surgery

Protocol summary

Study aim

Determination of injectable platelet-rich fibrin in post-operative healing after tooth crown lengthening surgery among patients referred to periodontal department of Guilan dentistry Faculty

Design

Clinical trial with control group, with parallel groups, single blind, Randomized to 16 patients with Randomization of permutation block method. Phase III trial

Settings and conduct

This is a single blind, split-mouth randomized controlled clinical trial study on patients referred to the periodontology department of Guilan Dental School who needed surgery to increase the crown length in the two posterior maxillary right and left maxillary posterior teeth. This procedure is performed on the basis of inclusion and exclusion criteria, divided to the intervention group and the control group. All patients will be explained about the routine surgical protocols and no further procedure is needed. Every patient deliberately enters the study and is told that when he leaves the study his treatment will not be incomplete and routine treatment will be performed.

Participants/Inclusion and exclusion criteria

Patients referred to the periodontology department of Guilan Dental faculty required crown lengthening surgery in two canines or maxillary right and left premolars were included in the study. Systemic problems affecting wound healing ,smokers and patients with coagulation problems were excluded.

Intervention groups

Study groups include: 1.Intervention group: crown lengthening Surgery and i-PRF injection under periodontal flap 2. Control group:crown lengthening Surgery and non-injection of i-PRF under periodontal flap

Main outcome variables

Tissue repair (based on early healing index) over days 2, 4, 7, 10 and 14; Postoperative pain (based on Visual Analogue Scale) over days 2, 4, 7, 10 and 14

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130813014350N3**
Registration date: **2020-05-24, 1399/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-24, 1399/03/04**
Update count: **0**

Registration date

2020-05-24, 1399/03/04

Registrant information

Name

Bardia Vadiati Saberi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1326 3622

Email address

bardia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-06, 1399/02/17

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of injectable platelet-rich fibrin in post-operative healing after tooth crown lengthening surgery

Public title
Effect of injectable platelet-rich fibrin in post-operative healing after tooth crown lengthening surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients need surgery for maxillary bilateral crown lengthening including canine and premolar teeth Patients over 18 years Lack of systemic disease that affects wound healing No history of surgery in the area of operation Non-smoker Non-pregnancy and lactation Not using antibiotics in the last 6 months
Exclusion criteria:
Coagulation Disorders Uncooperative patient Any complications that interfere with the postoperative recovery process and postoperative pain
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **16**
More than 1 sample in each individual
Number of samples in each individual: **2**
The right and left maxillary canine and premolar teeth
Randomization (investigator's opinion)
Randomized
Randomization description
The permutation block method is used to randomize treatments. Considering blocks of 4, respectively, people will be included in the study if A receives treatment on the right and B receives treatment on the left and the other is considered as control: Seed: 272654992542016 Block sizes: 4 Actual list length: 16 block identifier, block size, sequence within block, treatment, code • 1, 4, 1, Group A, ZN6 • 1, 4, 2, Group A, AA8 • 1, 4, 3, Group B, ZR9 • 1, 4, 4, Group B, TS5 • 2, 4, 1, Group A, PG3 • 2, 4, 2, Group A, ZS4 • 2, 4, 3, Group B, ZQ3 • 2, 4, 4, Group B, DG0 • 3, 4, 1, Group A, JR0 • 3, 4, 2, Group B, GS3 • 3, 4, 3, Group A, KG1 • 3, 4, 4, Group B, HQ6 • 4, 4, 1, Group A, RR5 • 4, 4, 2, Group B, FA1 • 4, 4, 3, Group B, KG7 • 4, 4, 4, Group A, ER9
Blinding (investigator's opinion)
Single blinded
Blinding description
The research will be conducted in single blinded manner. To blind the patient, the researcher performs all operations on the intervention side during surgery on the control side only at the time of i-PRF injection but does not inject the insulin needle.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of guilan University of Medical Sciences
Street address
Bustan Mellat, Ahmadzadeh Blvd., Shahid Amini Alley, Parvaneh dead end, No. 103, Rose Building
City
Rasht
Province
Guilan
Postal code
4174734681
Approval date
2020-05-06, 1399/02/17
Ethics committee reference number
IR.GUMS.REC.1399.060

Health conditions studied

1

Description of health condition studied
Evaluation of injectable platelet-rich fibrin in post-operative healing after tooth crown lengthening surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Surgical Pain
Timepoint
2,4,7,10,14 days
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Tissue repair
Timepoint

2,4,7,10,14 days

Method of measurement

Early healing index

Intervention groups

1

Description

Intervention group: Gingival surgery to increase the length of the crown and in order to, injecting 1 cc of i-PRF (from 10 cc of the patient's blood in the centrifuge device (DR. CHOUKROUN DUO QUATTRO PRF CENTRIFUGE) speed 700 rpm for 3 minutes And the clear part of the fluid above the tube (i-PRF) with the insulin syringe stretched) in the patient's gums.Clinical postoperative examinations and photographic imaging are performed using the Visual Analogue Index as the primary outcome and the Early Healing Index scale as the secondary outcome on days 2, 4, 7, 10, and 14.

Category

Treatment - Surgery

2

Description

Control group: Gingival surgery in order to increase the length of the tooth crown without injecting any substance was performed .Clinical postoperative examinations and photographic imaging are performed using the Visual Analogue Index as the primary outcome and the Early Healing Index scale as the secondary outcome on days 2, 4, 7, 10, and 14.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan Dental faculty

Full name of responsible person

bardia vadiati

Street address

Lacan 2 km Saravan Road to Fouman, School of Dentistry

City

Rasht

Province

Guilan

Postal code

4188794755

Phone

+98 13 3348 6406

Email

dental@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Research Centre, Guilan University of Medical Sciences

Full name of responsible person

seedeh sana alavi

Street address

Vice chancellor for Research and Technology building, Imam Khomeini Avenue, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4188794755

Phone

+98 13 3348 6406

Email

dental@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dental Research Centre, Guilan 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

Rasht University of Medical Sciences

Full name of responsible person

Bardia Vadiati Saberi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Street address

Faculty of Dentistry, Guilan University of Medical Sciences, Ring Fooman, Lacan Road, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4188794755

Phone

+98 13 1326 3622
Fax
+98 13 1326 3623
Email
bardia@gums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Bardia Vadiati Saberi
Position
Assistant
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Faculty of Dentistry, Guilan University of Medical Sciences, Ring Fooman, Lacan Road, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4194173774
Phone
+98 13 1326 3622
Fax
+98 13 1326 3622
Email
bardia@gums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Bardia Vadiati Saberi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Street address
Faculty of Dentistry, Guilan University of Medical Sciences, Ring Fooman, Lacan Road, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4188794755
Phone
+98 13 1326 3622
Fax
+98 13 1326 3623
Email
bardia@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Evaluation of injectable platelet-rich fibrin in post-operative healing after tooth crown lengthening surgery among patients referred to periodontal department of Guilan dentistry Faculty
When the data will become available and for how long
Access time 6 months after publishing the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Researchers working in academic institutions
From where data/document is obtainable
Bardia@gums.ac.ir
What processes are involved for a request to access data/document
2 months
Comments