

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of injection of platelet-rich fibrin gel (Alb-PRF) and hyaluronic acid filler on interdental papilla reconstruction, a randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of injection of platelet-rich fibrin gel and hyaluronic acid filler on interdental papilla reconstruction

Design

This study is a clinical trial with two intervention groups: injection of hyaluronic acid filler and platelet-rich fibrin gel in the interdental papilla. This double-blind study will be performed on 66 patients (33 patients in each group with a 20% reduction in probability and 26 patients in each group). For randomization, the block randomization method with the size of 4 and 6 blocks in both intervention and control groups is used.

Settings and conduct

In this study, hyaluronic acid or Alb-PRF gel prepared from the peripheral blood of patients was randomly injected into the analyzed interdental papillae of Nordland Class I and II. Alb-PRF is prepared according to the protocol by preparing 9 ml of whole blood without adding any additives. Papillary changes will be assessed by photograph and Williams periodontal probe at 0, 3 and 6 months. At the end of month 6, patients' satisfaction with the beauty of appearance will be assessed using the Visual Analogue Scale (VAS) from 0 to 100 according to the patients' initial clinical pictures.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Conscious written consent to participate in the study at least one incomplete papilla Class I or II papillary defects according to the Nordland and Tarnow classifications Probing depth ≤ 4 mm Criteria for non-inclusion in the study: Gingivitis or periodontium History of periodontal surgery in the last 6 months in the area Open interdental contact (diastem) in the area Taking medications that cause gingival hyperplasia

Intervention groups

1. Hyaluronic acid group 2. Platelet-rich fibrin gel group

Main outcome variables

Filling of interdental papilla; interdental hygiene promotion; esthetics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130813014350N4**

Registration date: **2022-04-06, 1401/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-06, 1401/01/17**

Update count: **0**

Registration date

2022-04-06, 1401/01/17

Registrant information

Name

Bardia Vadiati Saberi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of injection of platelet-rich fibrin gel (Alb-PRF) and hyaluronic acid filler on interdental papilla reconstruction, a randomized clinical trial

Public title

Comparison of the effect of injection of platelet-rich fibrin gel and hyaluronic acid filler on interdental papilla reconstruction, a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Written informed consent to participate in the study
Having at least one deficient papilla Class I or II papillary defects according to the Nordland and Tarnow classifications Probing depth ≤ 4 mm Age between 20-75

Exclusion criteria:

Gingivitis or periodontitis Diabetes, connective tissue diseases and other systemic diseases affecting periodontal tissues History of allergic reaction Pregnant and lactating women History of periodontal surgery in the area in the last 6 months Open contact (diastem) in the area Medications that cause gingival hyperplasia

AgeFrom **20 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **33****Randomization (investigator's opinion)**

Randomized

Randomization description

Block randomization method with 4 and 6 block sizes will be performed in both intervention and control groups. It should be noted that if the patient has more than one eligible incomplete papilla, these papillae are assigned to the same treatment group. Random allocation sequence generation is done using the site www.sealedenvelope.com. Allocation concealment is performed using opaque numbered, stamped and sealed randomly sequenced (SNOSE) envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This test will be double-blinded. In this study, due to blood sampling in one group, it is not possible to blind the patient, and in any case, the patient will know in which group he will be studied. Also, due to the apparent difference between the two substances and the Alb-PRF preparation, it is not possible to blind the sample

allocator. Therefore, in the present study, the outcome evaluator is not aware of the injectable substance in each papilla. Also, the analyst of the study results will not know about the study groups. A code will be assigned to each of the treated papillae for statistical analysis.

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

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Province

Guilan

Postal code

4174734681

Approval date

2022-03-10, 1400/12/19

Ethics committee reference number

IR.GUMS.REC.1400.604

Health conditions studied**1****Description of health condition studied**

reconstruction of incomplete interdental papilla

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

Primary outcomes**1****Description**

interdental papilla fill (black triangle area change)

Timepoint

0, 3, 6 months

Method of measurement

Measure the area of black triangles at specified intervals and examine the area changes in Photoshop

Secondary outcomes

1

Description

Patients' satisfaction with the results of the intervention

Timepoint

at the end of the sixth month

Method of measurement

visual analogue scale

2

Description

Plaque index on the treated teeth

Timepoint

At the beginning and end of the study (0 and 6 months)

Method of measurement

Loe index, the amount of microbial plaque accumulated on the treated teeth (especially in the interproximal area)

Intervention groups

1

Description

The treatment protocol was divided into 3 stages: pre-injection stage, or examination, injection stage and follow-up stage. The first visit will begin with the collection of demographic information, medical history and dentistry. Conscious consent is signed by patients. Primary periodontal treatment includes scaling and debridement of the gums. Plaque index is recorded in the teeth of the treated area. The distance between the tooth contact and the bone crest is measured by parallel periapical radiography. Before starting the test, the interdental papilla is evaluated according to the Nordland and Tarnow classifications and will be recorded in the relevant tables. Clinical photographs perpendicular to the target teeth will also be taken. Black triangles are measured clinically from the tip of the papilla to the point of interdental contact using a Williams periodontal probe and an acrylic stent... Intervention group: Hyaluronic acid filler injection..... After injection of local anesthesia, a hyaluronic acid filler with an approximate amount of less than 0.2 ml, 2-3 mm apical from the papilla tip and at an angle of 45 degrees to the longitudinal axis of the tooth will be injected with a 30 gauge insulin syringe. Patients will then be instructed in oral and written care after the injection. Patients are recalled in for a booster dose three weeks later.

Category

Treatment - Other

2

Description

Intervention group: Platelet-rich fibrin gel injection..... Preparation of Alb-PRF: From each patient, 9 ml of whole blood is collected in a plastic tube and immediately centrifuged at 700 g at room temperature

for 8 minutes. After centrifugation, the top 2 ml layer (PPP) is collected in 2 ml syringes and heated at 75 ° C for 10 minutes to prepare a denatured albumin gel. The tube is then allowed to reach room temperature again for 10 minutes. Liquid PRF (layer on RBC) containing residual cells and growth factors is mixed with albumin gel and Alb-PRF gel is prepared ready for injection.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan School of Dentistry

Full name of responsible person

Dr. Bardia Vadiati Saberi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht 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

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

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

Comparison of the effect of injection of platelet-rich fibrin gel and hyaluronic acid filler on interdental papilla reconstruction, a randomized clinical trial

When the data will become available and for how long

6-12 months after result publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use in higher level studies such as systematic review studies

From where data/document is obtainable

I Bardia@gums.ac.ir

What processes are involved for a request to access data/document

Documents for writing a review article (for example, an

invitation letter from the journal) should be provided
Comments