Does i-PRF (injectable platelet-rich fibrin) improve the quality of periodontal tissue and accelerate orthodontic tooth movement?

Submission date	Recruitment status	Prospectively registered
09/04/2024	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
15/04/2024	Completed	Results
Last Edited	Condition category	Individual participant data
23/06/2025	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Mandibular incisor crowding is a frequent issue that prompts many adults to seek orthodontic treatment. When teeth are crowded together, it can lead to various problems such as the wearing away of the roots, a reduction in the height and density of the bone on the outer side of the teeth, gaps forming between teeth, and the development of window-like gaps in the bone. Additionally, the width of the protective tissue around the teeth may decrease. Platelet-rich concentrates, like injectable platelet-rich fibrin, have been shown to have positive effects on both soft and hard tissue healing. They may serve as a beneficial self-derived material to prevent these complications.

Who can participate?

Adults aged 18-28 years old with skeletal class I malocclusion.

What does the study involve?

Participants will be divided randomly into three groups:

- 1. Experimental Group 1: In this group, platelet-rich fibrin (I-PRF) will be injected once into the space between the cheeks and the teeth on the lower jaw, specifically around the mandibular incisors.
- 2. Experimental Group 2: In this group, platelet-rich fibrin (I-PRF) will be injected four times into the same area around the mandibular incisors, with a 30-day gap between each session.
- 3. Control Group: Participants in this group will receive injections of a saline solution into the same area around the mandibular incisors. This is done to prevent any tingling sensation that might occur.

What are the possible benefits and risks of participating? Using this modified device may enhance the efficiency of crowded incisor alignment. There are no expected risks of participating.

Where is the study run from? Damascus University (Syria)

When is the study starting and how long is it expected to run for? June 2022 to April 2025

Who is funding the study? Damascus University (Syria)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2723

Study information

Scientific Title

Effect of repeated injection of platelet-rich fibrin on crowded mandibular incisor alignment efficiency: a randomized controlled clinical trial

Acronym

i-PRF

Study objectives

- 1. I-PRF enhances the efficiency of crowded mandibular incisor alignment.
- 2. I-PRF accelerates orthodontic tooth movement.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/06/2022, Scientific research and postgraduate studies council of Damascus University (Mazzeh highway, Damascus, 80789, Syria; +963 (0)993303359; ap. srd@damascusuniversity.edu.sy), ref: 2723

Study design

Interventional single-center single-blinded randomized parallel-group controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Dental clinic

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

Malocclusion, Angle Class I; Crowded Teeth

Interventions

Patients will be randomly allocated into two groups using Microsoft® Excel electronic randomization:

Arm 1:

Experimental group 1: I-prf will injected in the buccal sulcus of the mandibular incisors 1 session directly after lower arch bracket adhesive. Orthodontic wires will be sequenced till reach to 19×25 ss.

Arm 2:

Experimental group 2: I-prf will injected in the buccal sulcus of the mandibular incisors 4 sessions with 30-day interval. Orthodontic wires will be sequenced till reach to 19×25 ss.

Arm 3:

Control group: . Saline serum will injected in the buccal sulcus of the mandibular incisors, to avoid the tingling effect. Orthodontic wires will be sequenced till reach to 19×25 ss.

Intervention Type

Biological/Vaccine

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Platelet-rich fibrin

Primary outcome measure

Dentoalveolar changes before and after treatment will be assessed using cone-beam computed tomography:

- 1. Dentoalveolar changes including:
- 1.1. Dehiscence in the buccal alveolar bone.
- 1.2. Fenestration in the buccal alveolar bone.
- 1.3. Height and thickness of alveolar bone.
- 2. Keratinized tissue width.
- 3. Lower arch alignment time.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

20/06/2022

Completion date

04/04/2025

Eligibility

Key inclusion criteria

- 1. Adult patients.
- 2. Class I malocclusion with moderate crowding (4-6) mm.
- 3. Good oral hygiene and periodontal health.
- 4. No severe skeletal discrepancy.
- 5. Normal or inclination for the upper and lower incisors.
- 6. No congenitally missing or extracted teeth (except for the third molars).

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

28 Years

Sex

Both

Target number of participants

54

Total final enrolment

54

Key exclusion criteria

- 1. Patients with syndromes or craniofacial abnormalities.
- 2. Patients with vertical growth patterns.
- 3. Poor oral hygiene.
- 4. Previous orthodontic treatment.

Date of first enrolment

01/08/2023

Date of final enrolment

04/04/2024

Locations

Countries of recruitment

Syria

Study participating centre Damascus university

Department of orthodontics Faculty of Dentistry Al-Mazzeh St. Damascus Syria 80789

Sponsor information

Organisation

Damascus University

Sponsor details

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Sponsor type

University/education

Website

http://damasuniv.edu.sy/

ROR

https://ror.org/03m098d13

Funder(s)

Funder type

University/education

Funder Name

Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

12/12/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date