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

Submission date
09/04/2024

Recruitment status
No longer recruiting

Registration date
15/04/2024

Overall study status
Completed

Last Edited
23/06/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[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
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Sponsor type
University/education

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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