ISRCTN18306557 https://doi.org/10.1186/ISRCTN18306557

Platelet-rich plasma injections and periodontal health

Submission date	Recruitment status	[_] Prospectively registered
29/08/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/08/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/08/2024	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study was to evaluate the effects of platelet-rich plasma (PRP) injections, a method of accelerating orthodontic tooth movement, on the health of periodontal (gum) tissues.

Who can participate?
Patients aged 18 to 25 years with anterior teeth crowding.

What does the study involve?
Participants are randomly assigned to either the PRP group or the control group. The PRP group received PRP injections at 0, 7, and 14 days, while the control group received standard orthodontic treatment without additional interventions. Periodontal health was evaluated at the start of the study and after 4, 8 and 12 weeks.

What are the possible benefits and risks of participating?
This study will evaluate the effects of PRP injection to accelerate orthodontic tooth movement on periodontal health. There is a risk of not achieving optimal results in some cases but the study team can manage these cases with alternative methods.

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

When is the study starting and how long is it expected to run for?
November 2021 to August 2023

Who is funding the study?
Tishreen University (Syria)

Who is the main contact?
Dr May Alel, akeelmai035@gmail.com

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
2608

Study information

Scientific Title
Platelet-rich plasma injections and periodontal health: effects during accelerated orthodontic tooth movement

Study objectives
Does platelet-rich plasma injections during accelerated orthodontic tooth movement affect periodontal health

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/12/2021, Tishreen University ethics committee (Lattakia, Lattakia, 0000, Syria; +963 (0)41420291; info@tishreen.edu.sy), ref: 2068

Study design
Comparative interventional randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Quality of life, Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Anterior teeth crowding

Interventions
Participants are randomly assigned to either the PRP group or the control group. Randomization was achieved using sealed envelopes containing the allocation sequence, ensuring that treatment assignments remained concealed from both researchers and participants until the designated phase of the study. The randomization sequence was generated by an independent academic specialist.

The PRP group received PRP injections at 0, 7, and 14 days, prepared using the double-spin method, while the control group received standard orthodontic treatment without additional interventions. Periodontal health parameters were evaluated at baseline and at 4, 8 and 12 weeks. Aspartate aminotransferase (AST) levels were assessed at baseline, 1 hour, 1 day, 7 days, and 14 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
Salivary aspartate aminotransferase (AST) activity measured using a spectrophotometer at baseline (before treatment), 1 hour after the start of treatment, 1 week after, and 2 weeks after treatment

Secondary outcome measures
Periodontal health parameters, including Periodontal Pocket Depth (PPD), Clinical Attachment Level (CAL), Bleeding on Probing (BOP), and Gingival Recession (GR), were recorded using a UNC-15 periodontal probe at baseline, 4 weeks, 8 weeks, and 12 weeks.

Overall study start date
13/11/2021

Completion date
23/08/2023

Eligibility

Key inclusion criteria
1. Individuals aged 18 to 25 years with anterior teeth crowding ranging from 3 to 6 mm
2. Maintaining excellent oral hygiene and periodontal health
3. Without prior orthodontic treatment history

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Systemic medical conditions
2. Dental anomalies in tooth size or shape
3. Current use of anti-inflammatory medications

Date of first enrolment
01/01/2022

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
Syria

Study participating centre
Tishreen University
Lattakia
Lattakia

Syria
0000

Sponsor information

Organisation
Tishreen University

Sponsor details
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+963 (0)41420291
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Sponsor type
University/education

Website
http://en.tishreen.edu.sy/

ROR
https://ror.org/04nqts970

Funder(s)

Funder type
University/education

Funder Name
Tishreen University

Alternative Name(s)
October University, Université Tichrine, , TU

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
15/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Dr May Alel (akeelmai035@gmail.com) and in the publication related to it after the end of the research.

IPD sharing plan summary
Available on request