Analyzing the impact of injecting platelet-rich plasma on molar tooth movement

Submission date	Recruitment status	Prospectively registered
24/03/2024	No longer recruiting	☐ Protocol
Registration date 26/03/2024	Overall study status Completed	Statistical analysis plan
		Results
Last Edited	Condition category Oral Health	Individual participant data
26/03/2024		Record updated in last year

Plain English summary of protocol

Background and study aims

The utilization of platelet-rich plasma (PRP) in dentistry has been ongoing for several decades. However, its practical application in orthodontics still demands more thorough examination. The objective of this research was to assess the potential impacts of injecting PRP locally on the speed and nature of movement of mandibular second molars forward compared to a control group.

Who can participate?

Patients aged 17 - 25 years who require lower molar protraction

What does the study involve?

Patients were randomly chosen to participate in a study where their mouths were divided into two halves. One half received injections of platelet-rich plasma (PRP) before starting the protraction process (PRP group), while the other half received only saline solution (comparator group). To be eligible for the study, patients needed to have their lower first molars removed on both sides for at least a year, and their lower second molars needed to be ready for protraction. The main focus of the study was to measure how quickly the molars moved forward from the beginning of the protraction process until the end of the seventh month, using a digital gauge. Another aspect was to determine the type of movement of the second molars during protraction by examining side-view X-ray images before protraction (T0) and after seven months (TF). The decision about which side received the PRP injection was made randomly by selecting envelopes that were opaque and sealed. While it wasn't possible to keep the principal investigator unaware of the treatment, the patients were kept unaware by injecting saline solution on the other side.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? University of Aleppo (Syria)

When is the study starting and how long is it expected to run for? September 2020 to February 2024

Who is funding the study? University of Aleppo (Syria)

Who is the main contact? amerkhatib82@gmail.com ferasbaba72@gmail.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

researchregistry9722

Study information

Scientific Title

Evaluating the injection of platelet-rich plasma on second lower molars protraction: a randomized controlled clinical trial

Study objectives

Injection of PRP accelerates lower molar protraction

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 08/03/2020, University of Aleppo Ethics Committee (Dental College, University of Aleppo, Aleppo, -, Syria; -; sr.srd@damascusuniversity.edu.sy), ref: UADS-2401-08032020/SRC-1036

Study design

Interventional randomized controlled clinical trial split mouth design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

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

Patients with bilaterally extracted mandibular first molars

Interventions

Patients were randomly allocated in a split-mouth study design to receive PRP injections on one side (PRP group) immediately before the start of protraction, while the other side received only saline solution (comparator group).

20 ml of blood was directly collected by butterfly scalp vein from the patient to sterile tubes

with ACD-A as an anticoagulant. One millilitre of the blood sample was set apart to determine the concentration of platelets. PRP was prepared by the double-spin technique as described by Marx and Garg with modifications; initially, the blood was centrifuged at 1600 rpm for 4 minutes to separate the plasma containing the platelets from the red cells. The plasma was drawn off the top and centrifuged for an additional 6 minutes at 3500 rpm to get PRP. Follow up for 7 months.

Intervention Type

Biological/Vaccine

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Platelet-rich plasma

Primary outcome measure

Rate of molar protraction from the beginning of protraction and the end of the seventh month, using a digital gauge

Secondary outcome measures

Type of movement of second molar protraction by lateral cephalometric images before molar protraction (T0) and after seven months of molar protraction (TF)

Overall study start date

01/09/2020

Completion date

10/02/2024

Eligibility

Key inclusion criteria

- 1. Aged between from 17 and 25 years
- 2. Have all lower permanent teeth present, including intact third molar, but the bilateral first permanent lower molar were extracted and indicated mandibular second molars protraction, in which extractions were done at least one year ago to ensure complete extraction socket cortication and at most 3 years to avoid severely inclined second lower molars, or severely reduced alveolar bone height and width

Participant type(s)

Patient

Age group

Adult

Lower age limit

Upper age limit

25 Years

Sex

Both

Target number of participants

18

Total final enrolment

15

Key exclusion criteria

- 1. Have undergone previous orthodontic treatment
- 2. Have poor oral hygiene
- 3. Systemic disease especially those with coagulation problems or who are being treated with anticoagulants and NSAIDS
- 4. Unilateral chewing or extra-functional habits.

Date of first enrolment

01/09/2020

Date of final enrolment

10/01/2022

Locations

Countries of recruitment

Syria

Study participating centre Aleppo University

Shahbaa street Aleppo Syria 15310

Sponsor information

Organisation

University of Aleppo

Sponsor details

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Sponsor type

University/education

Website

http://www.alepuniv.com/

ROR

https://ror.org/03mzvxz96

Funder(s)

Funder type

University/education

Funder Name

University of Aleppo

Alternative Name(s)

Aleppo University, , UOA

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

01/06/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request amerkhatib82@gmail.com

IPD sharing plan summary

Available on request