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The effect of platelet-rich plasma and laser in reducing post-operative complications after lower third molar extraction

Submission date	Recruitment status	[ ] Prospectively registered
02/04/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/04/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/04/2024	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Extraction of impacted third molars is one of the most common surgical procedures in dental clinics, often accompanied by post-operative complications such as pain, discomfort, swelling (edema) and a locked jaw (trismus). Many surgeons tend to prescribe painkillers, non-steroidal anti-inflammatory drugs and corticosteroids after surgery and sometimes these medications have side effects. Many prior studies have sought alternative approaches to reduce these complications such as platelet-rich plasma (PRP), platelet-rich fibrin (PRF), low-level laser (light) therapy (LLLT) and aloe vera gel. This study aims to investigate the combined effect of PRP and LLLT in reducing post-operative complications and evaluate the post-surgical healing process.

Who can participate?
Healthy adults diagnosed with impacted lower third molars indicated for extraction

What does the study involve?
This study compares the effectiveness of PRP combined with a diode laser, PRP alone, or no treatment (as a control group) in reducing post-operative complications following the extraction of lower third molars. It will involve 22 patients aged between 18 and 26 years old, all diagnosed with impacted lower third molars requiring surgical extraction on both sides. Patients will be selected based on specific inclusion and exclusion criteria.

What are the possible benefits and risks of participating?
PRP and LLLT have proven effects on reducing pain and accelerating the healing process.

The surgical procedure may be accompanied by pain, edema, bleeding after surgery, and discomfort. As for PRP preparation, there is a potential risk when collecting blood such as bruising after drawing blood and patient dizziness.

Where is the study run from?
Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University, Syria

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

Who is the funding of the study?
Damascus university

Who is the main contact?
Dr Rita Alsaleh, rorialsaleh@gmail.com, rita1995.alsaleh@damascusuniversity.edu.sy

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
163

Study information

Scientific Title

Reducing post-operative complications after impacted lower third molars surgical extraction using platelet-rich plasma (PRP) in combination with diode laser (660 nm). Randomized Controlled Trial (RCT)

Study objectives
H0: there are no significant differences among the studied groups in reducing post-operative complications of lower third molars extraction in the studied indices.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/09/2021, Ethics Scientific Committee at Damascus University (Baramkeh, Damascus, 4671, Syria; +963(11)33923223; ap.srd@damascusuniversity.edu.sy), ref: 2255

Study design
Split-mouth randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Impacted lower third molars

Interventions
This study is designed to compare the efficacy of platelet-rich plasma (PRP) in combination with diode laser, PRP alone, and a control group (no additional procedure as a control group) in minimizing post-operative complications after surgical extraction of lower third molars. A total of 22 patients, aged between 18 and 26 years old, diagnosed with impacted lower third molars requiring bilateral surgical extraction, will be selected to participate based on strict inclusion and exclusion criteria.

Methodology:
The randomization method uses sealed envelopes to allocate participants into one of the three intervention groups: PRP with diode laser, PRP alone, or control group. The study comprises three appointments for each participant:

First Appointment: During this initial visit, blood is drawn from the participants for PRP preparation, and the surgical extraction procedure is performed.

Second Appointment: Scheduled for the assessment of post-operative edema and trismus, this appointment allows for the immediate monitoring of the effects of the interventions.

Third Appointment: Dedicated to evaluating the healing process post-extraction, this appointment facilitates the assessment of the long-term outcomes of the interventions.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain measured using a Visual Analogue Scale (VAS) on the procedure day and daily on the first 7 days following the procedure

Key secondary outcome(s))
1. Edema measured using the tape method (the distance from the corner of the mouth to the attachment of the earlobe following the bulge of the cheek and the distance from the outer canthus of the eye to the angle of the mandible) at baseline, 3 days, and 7 days following the procedure
2. Healing index measured using the Gingival Healing Index (GHI) on one timepoint 7 days post-operatively
3. Trismus measured using the Maximum Interincisal Opening (MOI) at baseline, 3 days, and 7 days following the procedure

Completion date
02/05/2023

Eligibility

Key inclusion criteria
1. Aged between 18-30 years old
2. Require extraction of impacted lower third molars (asymptomatic, bilateral and indicated extractions (poorly placed, orthodontic reasons) and symmetrical (the angle, and difficulty of extraction))
3. Healthy patients that have no systemic diseases that may affect the healing process
4. The surgical condition should be as similar as possible among the group (e.g. extraction time)
5. Able to give consent to enroll in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Total final enrolment
22

Key exclusion criteria

1. Pre-existing medical condition that is considered a surgery contraindication
2. Pregnancy and lactation
3. Allergies to some medication (Paracetamol, Chlorhexidine)
4. Severe TMJ disorders
5. Chronic or neurological pain, and psychological disorders
6. Light sensitivity

Date of first enrolment
03/04/2022

Date of final enrolment
25/04/2023

Locations

Countries of recruitment
Syria

Study participating centre
Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University
Mazzeh Highway
Damascus
Syria
4671

Sponsor information

Organisation
Damascus University

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr Rita Alsaleh, rorialsaleh@gmail.com, rita1995.alsaleh@damascusuniversity.edu.sy.

The type of data that will be shared includes the patient information sheet, and any data except any personal information such as demographic details, or any photo that can determine the patient's identity. The timing of availability is after publication in a high-impact journal. Consent from participants was required and was obtained from each patient. Any personal data will be anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/04/2024	No	Yes
Participant information sheet			10/04/2024	No	Yes
Participant information sheet			10/04/2024	No	Yes