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Evaluation of topical ozonated olive oil gel on socket healing after surgical extraction of impacted molars

Submission date
15/05/2023

Recruitment status
No longer recruiting

Registration date
22/05/2023

Overall study status
Completed

Last Edited
22/05/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The objective of this study is to evaluate the effects of ozonated olive oil gel in bone and soft tissue healing and prevention of alveolitis when applied within the socket after surgical extraction of the impacted mandibular third molars.

Who can participate?
Healthy adults with symmetrically impacted mandibular third molars on both sides

What does the study involve?
In this prospective split-mouth study, 36 extractions will be performed in 18 patients. On one side, the socket will be primarily (control side) sutured, and on the other side, ozonated olive oil gel will be inserted before suturing. The patients will be assessed for postoperative bone regeneration, soft tissue healing alveolitis and periodontal integrity of the mandibular second molar.

The primary outcome will be bone regeneration, which is measured through tomographic evaluation 6 weeks and 3 months after the procedure. The ITK-SNAP software was used for image evaluation by the intensity of grey of each voxel. Soft tissue healing is analysed based on a modified healing index of Landry et al. and by comparing pre-and postoperative periodontal probing at the distal of the lower second molar.

What are the possible benefits and risks of participating?
The benefits of participating are the promotion and acceleration of healing of surgical wounds, the promotion of bone regeneration after surgical extraction, and improving the patient's quality of life after surgery. There are no expected risks of participating in this study except for the complications associated with a usual surgical extraction.

Where is the study run from?
Oral and Maxillofacial Surgery Department, Faculty of Dental Medicine, Damascus University (Syria)

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

Who is funding the study?
Oral and Maxillofacial Surgery Department, Faculty of Dental Medicine, Damascus University (Syria)

Who is the main contact?
Dr Zaher Jumaa, zaher.jumaa94@damascusuniversity.edu.sy

Contact information

Type(s)
Public

Contact name
Dr Zaher Jumaa

Contact details
Damascus Governorate
Damascus
Syria
22743
+963957957823
zahjm94@gmail.com

Type(s)
Scientific

Contact name
Dr Zaher Jumaa

Contact details
Damascus Governate
Damascus
Syria
22743
+963957957823
zaher.jumaa94@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
543216

Study information

Scientific Title
Evaluation of the efficacy of topical ozonated olive oil gel on socket healing after surgical extraction of impacted mandibular third molars

Study objectives
Ozonated olive oil gel has a good effect on the healing of bone tissue at the site of surgical extraction, healing of soft tissues at the site of surgical extraction, preserving the integrity of the periodontal tissues of the lower second molars after surgical extraction of the impacted lower third molars, and prevention of alveolitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2023, Scientific Research Ethics Committee in Presidency of Damascus University (Central Directorate of Students Affairs, Damascus University, Baramkeh, Damascus, Syria 22743; +963 11 33923000, +963 11 33923011; verification.dicr@damascusuniversity.edu.sy), ref: DN – 0592

Study design
Prospective randomized controlled trial split-mouth study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Study type(s)
Prevention, Quality of life, Treatment, Efficacy

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Promote bone and soft tissues healing and prevent alveolitis after surgical extraction of 3rd mandibular molar

Interventions
This study contains two groups in a split-mouth design (control side, experimental side) in healthy adult patients.
The researcher is responsible for the entire surgical procedure and application of the research

material, and the other observer is responsible for study measurements to avoid bias.
The researcher will apply 1 ml of ozonated olive oil gel into the extraction socket of the third mandibular molar on the first side and not apply it to the control side.

Intervention Type
Supplement

Primary outcome measure
1. Bone density measured using cone beam computed tomography (CBCT) imaging and ITK-SNAP software analysis at (t1) 6 weeks and (t2) 3 months after surgery
2. Soft tissue healing measured using Landry's index 7 days after surgery

Secondary outcome measures
1. Measurements using a periodontal probe at (t0) before surgery and (t2) 3 months after surgery
1.1. Probing depth (PD)
1.2. Gingival overgrowth (GO)
1.3. Clinical attachment level (CAL)
2. Incidence of alveolitis measured using the Blum index 7 days after surgery

Overall study start date
13/03/2023

Completion date
10/10/2023

Eligibility

Key inclusion criteria
1. Aged between 18 - 35 years old
2. Patients with symmetrically impacted mandibular third molar on both sides and of the same classification according to Pell & Gregory
3. Classification of general health status: ASA I (a normal, healthy, non-smoking patient with a normal body mass index) (American Society of Anesthesiologists, 2020)
4. Patients who are cooperative, have good mental ability and are committed to periodic reviews, postoperative recommendations and oral care
5. No previous surgical treatment of the target area
6. Patients with good oral health and healthy periodontal tissues

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
18

Key exclusion criteria
1. Patients with systemic disease affecting wound healing
2. Patients with fungal lesions in oral cavity
3. Presence of a periodontal injury in the lower second molar
4. Psychologically unstable patients
5. Patients who smoke
6. Uncooperative patients
7. The presence of local pathogens around the impacted molars, such as large cysts and tumors
8. The presence of any local or general contraindications to the use of ozonted olive oil gel such as systemic diseases, G6PD deficiency, or a history of allergy, local infection, a pregnant woman or using contraceptive drugs or breastfeeding, as well as recent myocardial infarction
9. Severe anemia
10. Hyperthyroidism

Date of first enrolment
10/04/2023

Date of final enrolment
10/09/2023

Locations

Countries of recruitment
Syria

Study participating centre
Oral and Maxillofacial Surgery Department - Faculty of Dental Medicine
Al-Mazzeh Highway
Damascus
Syria
22743

Sponsor information

Organisation
Damascus University

Sponsor details

Faculty of Dental Medicine
Al-Mazzeh Highway
Damascus Governorate
Syria
22743
+963 11 33923192
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://damascusuniversity.edu.sy/dent/

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

Intention to publish date
10/09/2024

Individual participant data (IPD) sharing plan

The datasets generated and analyzed during the current study will be included in subsequent results publication

No individual participant data will be shared. Results will be published by the investigators in academic journals. Sharing of generated study data will be carried out in several different ways. We plan to make our results available to researchers and potential collaborators interested in ozonated olive oil gel.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/05/2023	No	Yes