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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
15/05/2023		<pre>Protocol</pre>		
Registration date	Overall study status Completed Condition category Oral Health	Statistical analysis plan		
22/05/2023		Results		
Last Edited		Individual participant data		
22/05/2023		<ul><li>Record updated in last year</li></ul>		

#### 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

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# 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
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#### 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