

# Comparing collagen to collagen and hyaluronic acid in healing after impacted lower third molars surgical extraction

<b>Submission date</b> 11/06/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/07/2021	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to compare using collagen and hyaluronic acid on healing after impacted lower third molars surgical extraction.

### Who can participate?

Healthy adults aged 18 - 35 years who underwent bilateral impacted lower third molars surgical extraction

### What does the study involve?

Two impacted lower third molars will be extracted surgically for each patient. One will be filled with collagen, the other with collagen and hyaluronic acid. The visual analogue scales (VAS) scores, facial swelling, mouth opening, soft tissue healing and radial density of the bone will be assessed.

### What are the possible benefits and risks of participating?

It is crucial for maxillofacial surgeons to decrease the post-extraction complications and improve the third molar extraction socket healing by using a simple method. Both materials are safe and should not cause any additional risks. All participants will receive the same treatment.

### When is the study starting and how long is it expected to run for?

February 2022 to March 2022

### Where is the study run from?

Damascus University (Syria)

### Who is funding the study?

Damascus University (Syria)

### Who is the main contact?

Dr Moemeneh Bassam Kokash, moemena93@gmail.com

# Contact information

## Type(s)

Scientific

## Contact name

Dr Moemeneh Kokash

## ORCID ID

<http://orcid.org/0000-0002-2145-4218>

## Contact details

Mazzeh

Damascus

Syria

0096311

+963 945225923

[moemeneh3.kokash@damascusuniversity.edu.sy](mailto:moemeneh3.kokash@damascusuniversity.edu.sy)

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

MS711

# Study information

## Scientific Title

Effect of collagen and hyaluronic acid on healing after impacted lower third molars surgical extraction. (A clinical and radiographic study)

## Study objectives

We are trying to test the efficacy of collagen and hyaluronic acid on healing after impacted lower third molars surgical extraction.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 24/02/2020, Damascus University Rector (Baramkeh, Damascus, Syria; +966 55 506 3806; no email provided), ref: MS711

**Study design**

Split-mouth interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files (in Arabic)

**Health condition(s) or problem(s) studied**

Surgical extraction of symmetrical Impacted lower third molars

**Interventions**

This study is a split mouth randomized clinical trial. The patient chose a piece of coin to decide which side was to be applied collagen and which was to be applied collagen and hyaluronic acid in socket after impacted lower third molars surgical extraction.

Triangle full thickness flap was reflected and necessary bone removal was performed by slow-speed straight surgical headpiece with continuous irrigation of saline solution. After the impacted molar was removed and the socket was well rinsed with saline.

A randomized clinical trial was conducted, with one extraction socket being filled with collagen and the other extraction socket being filled with collagen and hyaluronic acid in the same patient. Patients returned after 1 week to have the sutures removed. They were followed up at 3 days, 7 days, 1 month, 3 months, and 6 months.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

At 3 days, 7 days, 1 month, 3 months, and 6 months:

1. Pain intensity measured using visual analogue scales (VAS)
2. Facial swelling (clinical evaluation)
3. Mouth opening (clinical evaluation)
4. Soft tissue healing (clinical evaluation)

**Secondary outcome measures**

Radial density measured using periapical digital radiographs at 1 month, 3 months and 6 months

**Overall study start date**

04/02/2020

**Completion date**

01/03/2022

## Eligibility

### Key inclusion criteria

1. The patient's age (18-35) years.
2. Surgical extraction of symmetrically impacted lower third molars is indicated.
3. Good general health and there are no uncontrolled systemic diseases.
4. The integrity of the periodontal tissues and the absence of periodontal diseases.
5. Good oral health.
6. There is no allergy or contraindication to the required postoperative prescription or to the applied medicinal substances.

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Upper age limit

35 Years

### Sex

Both

### Target number of participants

20

### Key exclusion criteria

1. Pregnant
2. Diabetes mellitus
3. Hypertension
4. Compromised immune system or other systemic diseases
5. Patients with pericoronitis, infection, pathological condition in the region of surgery

### Date of first enrolment

01/10/2020

### Date of final enrolment

01/09/2021

## Locations

### Countries of recruitment

Syria

**Study participating centre**  
**Damascus University**  
Clinics of Oral and Maxillofacial Department  
Mazzah High Way  
Damascus  
Syria  
0096311

## **Sponsor information**

**Organisation**  
Damascus University

**Sponsor details**  
Damascus University Rector  
Baramkeh  
Damascus  
Syria  
0096311  
+963 1133923192  
info@damascusuniversity.edu.sy

**Sponsor type**  
University/education

**Website**  
<http://damasuniv.edu.sy/>

**ROR**  
<https://ror.org/03m098d13>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
Damascus University

## **Results and Publications**

**Publication and dissemination plan**

After finishing the follow up procedure and writing the article, I am planning to publish it (with all results, statistical analysis and some photos) in Damascus University's journal, and many other international journals.

### **Intention to publish date**

01/03/2023

### **Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication

### **IPD sharing plan summary**

Other

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			06/07/2021	No	Yes
<a href="#">Protocol file</a>			06/07/2021	No	No