

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

Submission date 11/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/07/2021	Condition category 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

35 years

Sex

All

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

ROR

https://ror.org/03m098d13

Funder(s)

Funder type

University/education

Funder Name

Damascus University

Results and Publications

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

[Participant information sheet](#)

[Protocol file](#)

Details	Date created	Date added	Peer reviewed?	Patient-facing?
		06/07/2021	No	Yes
		06/07/2021	No	No