ISRCTN16820104 https://doi.org/10.1186/ISRCTN16820104

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

Submission date	Recruitment status	[_] Prospectively registered
11/06/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/07/2021	Oral Health	[_] 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

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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 filed 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
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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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?
Participant information sheet			06/07/2021	No	Yes
Protocol file			06/07/2021	No	No