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The effect of chamomile on healing and complications after tooth removal.

Submission date	Recruitment status	[_] Prospectively registered
16/02/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2023	Oral Health	[_] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aims to evaluate the application of chamomile on healing and complications after surgical extraction of impacted lower third molars.
Sometimes a wisdom tooth becomes stuck below the surface of your gums (impacted), and grows at an odd angle, possibly causing complications. Impacted wisdom teeth are third molars at the back of the mouth that don't have enough room to emerge or develop normally.

Who can participate?
Healthy adults aged 18 – 28 years who underwent surgical extraction of bilateral impacted lower third molars

What does the study involve?
Two impacted lower third molars will be extracted surgically for each patient. One will be filled with chamomile gel, the other with placebo gel. The visual analogue scales (VAS) scores, facial swelling, mouth opening, and soft tissue healing will be assessed over 7 days.

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 gels are safe and should not cause any additional risks. All participants will receive the same treatment.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
September 2020 to April 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mohammed Qassem Abo Rokbah, aborokbahmohammed94@gmail.com

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
3126

Study information

Scientific Title
Evaluation of the effect of topical application of chamomile after surgical extraction of impacted lower third molars: a clinical study

Study objectives
We are trying to test the efficacy of topical application of chamomile on healing and complications after impacted lower third molars surgical extraction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/09/2020, Damascus University Rector (Baramkeh, Damascus, Syria; +966 555063806;no email provided), ref:2948/SM

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
Pain, swelling and healing following surgical extraction of symmetrical impacted lower third molars

Interventions
This study is a split mouth randomized clinical trial. Both chamomile gel and placebo gel were colored red and loaded in coded syringes ("A" and "B") in equal quantities (2 ml), the researcher and the patients don't know which one is chamomile.
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 chamomile gel and the other extraction socket being filed with placebo gel ("A" and "B") in the same patient. Patients returned after 1 week to have the sutures removed. They were followed up at 3 and 7 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
At 3 and 7 days.
1. Pain 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
There are no secondary outcome measures

Overall study start date
07/09/2020

Completion date

01/04/2023

Eligibility

Key inclusion criteria
1. Age 18-28 years
2. Indication for surgical extraction of impacted lower third molars in a symmetrical position according to the classification of Pell & Gregory
3. Good general health and there are no uncontrolled systemic diseases
4. Good oral health
5. No previous pain
6. No allergy or contraindication to the required postoperative prescription or to the Plants of Asteraceae/compositae family

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
28 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Pregnancy or current menstraution
2. Uncontrolled diabetes, uncontrolled hypertension, neoplasms, known neuropsychiatric illness, blood dyscrasia, coagulation disorders, or metabolic disorders
3. Compromised immune system or other systemic diseases
4. Patients with pericoronitis, infection, pathological condition in the region of surgery

Date of first enrolment
11/01/2021

Date of final enrolment
30/03/2022

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

Website
http://damasuniv.edu.sy/

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
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
01/03/2024

Individual participant data (IPD) sharing plan
Available on request (aborokbahmohammed94@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Arabic		04/04/2022	No	Yes
Protocol file			04/04/2022	No	No