

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

Submission date 16/02/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/02/2023	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 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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 filled 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(s)

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)

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

28 years

Sex

All

Key exclusion criteria

1. Pregnancy or current menstruation
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

Syria

0096311

Sponsor information**Organisation**

Damascus University

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

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