

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

<b>Submission date</b> 16/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/02/2023	<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 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](mailto:aborokbahmohammed94@gmail.com)

# Contact information

## Type(s)

Scientific

## Contact name

Dr Mohammed Abo Rokbah

## ORCID ID

<https://orcid.org/0000-0001-7201-1284>

## Contact details

Al zahira

Damascus

Syria

-

+963 957590786

[mohammed8.aborokbah@damascusuniversity.edu.sy](mailto:mohammed8.aborokbah@damascusuniversity.edu.sy)

# Additional identifiers

## 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?
<a href="#">Participant information sheet</a>	in Arabic		04/04/2022	No	Yes
<a href="#">Protocol file</a>			04/04/2022	No	No