

# A comparison of recovery after impacted wisdom tooth removal

<b>Submission date</b> 01/11/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/11/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The surgical removal of impacted wisdom teeth (third molars) is one of the most common procedures in oral surgery. However, patients often experience swelling (facial edema), limited mouth opening (trismus), and pain after the operation. These symptoms are usually managed with anti-inflammatory medications such as corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs). While effective, these drugs can sometimes cause side effects, including stomach problems and kidney issues. This study aims to compare two alternative natural treatments, serratiopeptidase (an enzyme) and escin (a plant extract from horse chestnut), to see which is more effective in reducing swelling, pain, and trismus after wisdom tooth surgery when used together with standard medications.

### Who can participate?

Adults who are medically healthy and have two lower wisdom teeth (third molars) that need surgical removal can participate.

### What does the study involve?

This study uses a split-mouth design, meaning each participant acts as their own control. The two wisdom teeth will be removed in two separate surgeries, about three weeks apart.

- In one surgery, the participant will receive standard medications only (antibiotic, painkiller, and anti-inflammatory).
- In the other surgery, they will receive standard medications plus either serratiopeptidase or escin for five days after surgery.

The order and side (right or left) will be chosen randomly.

Measurements of mouth opening, facial swelling, and pain will be taken before surgery and on the 2nd, 3rd, and 5th days after each procedure.

### What are the possible benefits and risks of participating?

All treatments used are known to be safe and well-tolerated when taken as directed.

Participation will also contribute to improving clinical knowledge on safer alternatives for managing postoperative symptoms after wisdom tooth removal.

Participants may experience reduced swelling, pain, and discomfort following surgery, depending on the effectiveness of the treatment. The risks are minimal and mainly related to normal postoperative effects such as mild pain or swelling.

Where is the study run from?

The study is being conducted at the dental clinics of the College of Dentistry, University of Science and Technology, Sana'a, Yemen.

When is the study starting and how long is it expected to run for?

November 2023 to January 2025. The study began recruiting in July 2024 and was expected to run for approximately one year, including recruitment, follow-up, and data analysis.

Who is funding the study?

The research is self-funded by the investigator with institutional support from the University of Science and Technology, Yemen.

Who is the main contact?

Dr Arwa Mohammed Hussien Dahak (Principal Investigator), hamddahak@gmail.com, info@ust.edu.ye

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Ms Arwa Mohammed Hussien Dahak

### Contact details

University of Science and Technology  
Madhbah Roundabout, 60 Street  
Sana'a  
Yemen  
00000  
+967 (1) 373237  
hamddahak@gmail.com

## Additional identifiers

## Study information

### Scientific Title

Comparison of efficacy of serratiopeptidase and escin after impacted mandibular third molar surgery: a randomized controlled clinical trial

### Acronym

CESE-3M

### Study objectives

## General Objective

To compare the efficacy of serratiopeptidase and escin, when used as adjuncts to conventional drugs, in reducing postoperative complications (i.e., trismus, facial edema, and pain) following impacted mandibular third molar surgery.

## Specific Objectives

The study set the following specific objectives:

1. To evaluate the efficacy of serratiopeptidase, as an adjunct to conventional drugs, in reducing postoperative complications (i.e., trismus, facial edema, and pain) following impacted mandibular third molar surgery.
2. To evaluate the efficacy of escin, as an adjunct to conventional drugs in reducing postoperative complications (i.e., trismus, facial edema, and pain) following impacted mandibular third molar surgery.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 30/07/2024, University Research Ethics Committee (60th Street, Madhbah Roundabout, Sana'a, 00000, Yemen; +967 (1) 373237; info@ust.edu.ye), ref: 1445/0012/UREC /UST

## Study design

Split-mouth interventional triple-blind randomized controlled clinical trial

## Primary study design

Interventional

## Study type(s)

Efficacy, Treatment

## Health condition(s) or problem(s) studied

Postoperative complications—trismus, facial edema (swelling), and pain—in patients undergoing impacted mandibular third molar (wisdom tooth) extraction.

## Interventions

This is a triple-blind, split-mouth randomized controlled clinical trial. Each participant undergoes two separate impacted mandibular third molar extractions (one per side) and thus serves as their own control. On the first surgical visit, one side is treated with conventional postoperative medications plus an adjunct (either serratiopeptidase or escin), and after a three-week washout, the contralateral molar is extracted and treated with conventional medications alone, or vice versa. Participants are randomly assigned using sealed envelopes to determine which side and which treatment order they receive.

The interventions are:

- Experimental 1: Conventional medications plus oral serratiopeptidase 10 mg, administered immediately postoperatively and then three times daily for five days.
- Experimental 2: Conventional medications plus oral escin 20 mg, administered immediately postoperatively and then three times daily for five days.
- Control: Conventional medications alone (no enzyme/herbal adjunct).

Conventional medications given to all participants are Amoxicillin 500 mg twice daily, Metronidazole 500 mg three times daily, and Diclofenac sodium 50 mg twice daily as per the trial protocol.

Blinding and allocation: the study is triple-blind (patients, the evaluator, and the person analyzing outcomes are blinded; the operator performs surgery but is blind to evaluation data). Treatments are randomly allocated to sides/orders so that bias is minimized. Outcome measures include postoperative trismus, facial edema (swelling), and pain assessed at prespecified timepoints.

### 1. Facial Edema

Facial edema was assessed using the method described by Schultze-Mosgau et al. (1995) to quantitatively evaluate edema both before and after surgery. Measurements were taken with a flexible measuring scale while the patient maintained a closed-mouth position. Five fixed anatomical landmarks and three baseline reference lines were used for consistency:

Fixed points:

F1 – Tragus of the ear

F2 – Angle of the mandible

F3 – Soft tissue pogonion

F4 – Corner of the mouth

F5 – Lateral canthus of the eye

Baseline reference lines:

S1 – From tragus of the ear to corner of the mouth (Tr-Com)

S2 – From tragus of the ear to soft tissue pogonion (Tr-Pgo)

S3 – From lateral canthus of the eye to angle of the mandible (Lc-Gn)

### 2. Trismus

Trismus was evaluated by measuring the change in maximum mouth opening before and after the surgical procedure. Using a calibrated ruler, the distance between the incisal edges of the upper and lower central incisors was measured in millimeters

### 3. Pain Intensity

Pain intensity was evaluated both pre-operatively and post-operatively using a standardized 10-centimeter visual analogue scale (VAS), as described by Sirintawat et al. (2017). The scale ranged from 0, representing no pain, to 10, indicating the worst imaginable pain. At each assessment interval, patients reported the degree of pain they experienced on the scale, providing a simple yet reliable measure of subjective pain.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Serratiopeptidase, Serrapeptase, Escin, Aescine (OS: DCF), Sodium aescinate (IS)

## **Primary outcome(s)**

The following primary outcome measures were assessed before and after the surgical procedure:

1. Facial edema was measured using a flexible measuring scale while the patient maintained a closed-mouth position

2. Trismus was measured using the change in maximum mouth opening with a calibrated ruler (the distance between the incisal edges of the upper and lower central incisors was measured in millimeters)
3. Pain intensity was measured using a standardized 10-centimeter Visual Analogue Scale (VAS)

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

05/01/2025

## **Eligibility**

### **Key inclusion criteria**

1. Medically healthy
2. Presence of two mandibular third molars indicated for surgical extraction
3. No history of pericoronitis or other signs of inflammation within the past 30 days

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

All

### **Sex**

All

### **Total final enrolment**

24

### **Key exclusion criteria**

1. Current use of other medications such as NSAIDs or corticosteroids
2. Known allergy to any drugs administered in this study
3. Pregnancy or breastfeeding
4. History of diabetes or hypertension
5. Previous irradiation to the maxillofacial region
6. Intellectual disability or inability to attend follow-up visits
7. Presence of acute or subacute pericoronitis

### **Date of first enrolment**

30/07/2024

### **Date of final enrolment**

05/01/2025

## **Locations**

## Countries of recruitment

Yemen

## Study participating centre

**Dental Clinics at the College of Dentistry, University of Science and Technology, Yemen (USTY)**

60th Street, Madhbah Roundabout

Sana'a

Yemen

00000

## Sponsor information

### Organisation

University of Science and Technology, Sana'a

### ROR

<https://ror.org/0520msa48>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are not expected to be made available due to confidentiality concerns and institutional data protection policies of the University of Science and Technology, Yemen. The collected data contain identifiable clinical information that cannot be anonymized without risking patient privacy. However, summarized or aggregated data supporting the findings of this study may be made available from the corresponding author upon reasonable request and with approval from the institutional ethics committee.

### IPD sharing plan summary

Available on request