

# Efficacy of different over-the-counter analgesics for postoperative pain following oral biopsy

<b>Submission date</b> 26/09/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/09/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/09/2025	<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

Oral biopsies are small surgical procedures often needed to diagnose problems in the mouth. These procedures can cause pain afterwards. Many patients are treated with common painkillers such as paracetamol (acetaminophen) or ibuprofen, but it is not clear which works best. This study aimed to find out which commonly available medicine controls post-biopsy pain most effectively.

### Who can participate?

Adult patients scheduled for an oral biopsy at King Abdulaziz University Dental Hospital in Jeddah, Saudi Arabia.

### What does the study involve?

Participants were randomly placed into one of the three groups:

1. Paracetamol (1000 mg)
2. Ibuprofen (600 mg)
3. A combination tablet containing paracetamol (1000 mg), caffeine (60 mg), and codeine (18 mg).

Participants took the medication for 72 hours after their biopsy. Pain was measured at 4, 24, and 48 hours after the procedure using a standard 0–10 pain scale.

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

Benefits and risks not provided at registration.

### Where is the study run from?

Faculty of Dentistry, King Abdul Aziz University, Saudi Arabia.

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

April 2027 to March 2025

Who is funding the study?  
Faculty of Dentistry, King Abdul Aziz University, Saudi Arabia.

Who is the main contact?  
Dr Sara Akeel, sakeel@kau.edu.sa

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Sara Akeel

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Efficacy of different over-the-counter analgesics for postoperative pain following oral biopsy: a quasi-experimental study

### Study objectives

The objective of this study was to determine the efficacy of different OTC medications in the management of postoperative pain following oral biopsy to provide high-quality evidence on optimal first-line analgesia for patients following oral biopsies

### Ethics approval required

Ethics approval required

**Ethics approval(s)**

approved 25/12/2017, Research Ethics Committee, Faculty of Dentistry, King Abdul Aziz University (Alsuliamania, Jeddah, 21589, Saudi Arabia; +966126403443; den.faculty@kau.edi.sa), ref: 055-05-17

**Study design**

Interventional quasi-experimental parallel-group open-label study

**Primary study design**

Interventional

**Study type(s)**

Treatment, Efficacy

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

Postoperative pain following oral mucosal biopsy

**Interventions**

Patients will receive the following treatment for postoperative pain following oral mucosal biopsy:

Group A: Acetaminophen 1000 mg every 6 hours

Group B: Ibuprofen 600 mg every 6 hours

Group C: Combination acetaminophen 1000 mg + caffeine 60 mg + codeine 18 mg every 6 hours

Treatment duration: 72 hours post-biopsy

A comparative analysis of outcome variable pain scores will be undertaken between intervention groups at each time point (including post-hoc pairwise comparisons).

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Acetaminophen, ibuprofen, caffeine, codeine

**Primary outcome(s)**

Postoperative pain intensity measured using a Visual Analog Scale (VAS, 0–10) at 4, 24, and 48 hours after the biopsy procedure

**Key secondary outcome(s)**

Incidence of medication side effects or adverse events measured using data collected in Case Report Forms during the 72-hour treatment period

**Completion date**

13/03/2025

# Eligibility

## Key inclusion criteria

1. Adults (18–90 years)
2. Scheduled for oral biopsy at KAU-FD
3. Capacity to judge pain

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Mixed

## Lower age limit

18 years

## Upper age limit

90 years

## Sex

All

## Total final enrolment

44

## Key exclusion criteria

1. Patients with pain at baseline
2. Currently on pain or mood-altering medications
3. Allergic to any of the medications

## Date of first enrolment

30/04/2018

## Date of final enrolment

30/04/2024

# Locations

## Countries of recruitment

Saudi Arabia

## Study participating centre

King Abdulaziz University  
Alsuliamania Dist  
Jeddah

Saudi Arabia  
21589

## Sponsor information

### Organisation

King Abdulaziz University

### ROR

<https://ror.org/02ma4wv74>

## Funder(s)

### Funder type

University/education

### Funder Name

King Abdulaziz University

### Alternative Name(s)

, L'université du Roi Abdulaziz, La Universidad Rey Abdulaziz, King Abdulaziz University of Saudi Arabia, KAU

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

Saudi Arabia

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analyses during the current study will be available upon request from Dr Sara Akeel, [sakeel@kau.edu.sa](mailto:sakeel@kau.edu.sa)

### IPD sharing plan summary

Available on request