

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

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

ORCID ID

<https://orcid.org/0000-0001-8006-1185>

Contact details

King Abdulaziz University
Alsulaimanyah
Jeddah
Saudi Arabia
21589
+966126952000
sakeel@kau.edu.sa

Additional identifiers

Clinical Trials Information System (CTIS)

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 Unirversity

Alsuliamania Dist

Jeddah

Saudi Arabia

21589

Sponsor information

Organisation

King Abdulaziz University

ROR

<https://ror.org/02ma4ww74>

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

IPD sharing plan summary

Available on request