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

Submission date 26/09/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 26/09/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/09/2025	**Condition category** Oral Health	[_] Individual participant data [X] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Dental clinic

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Acetaminophen, ibuprofen, caffeine, codeine

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

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

Overall study start date
24/04/2017

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
75

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

Sponsor details
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Sponsor type
University/education

Website
https://www.kau.edu.sa/ar

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

Publication and dissemination plan
The results have been submitted for peer-review publication in BMC Oral Health.

Intention to publish date
30/10/2025

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