ISRCTN70034520 https://doi.org/10.1186/ISRCTN70034520

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

Submission date
26/09/2025

Recruitment status
No longer recruiting

Registration date
26/09/2025

Overall study status
Completed

Last Edited
26/09/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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

Primary study design
Interventional

Study design
Interventional quasi-experimental parallel-group open-label study

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/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

IPD sharing plan summary
Available on request