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Clinical efficacy of acacia nilotica (Arabic gum) extract on prevention of dry socket after impacted lower third molar surgery: a randomized controlled trial

Submission date
12/04/2025

Recruitment status
No longer recruiting

Registration date
22/04/2025

Overall study status
Completed

Last Edited
22/04/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Surgical extraction of impacted teeth can be associated with multiple postoperative complications like pain, swelling, trismus (lockjaw), and alveolar osteitis (dry socket). Clinicians therefore have adopted various interventions over the years to minimize these postoperative complications with varying degrees of success. The aim of this study was to assess the effectiveness and safety of A. nilotica in controlling post-interventional complications (pain, inflammation, trismus, amount of analgesics required and overall wound healing) in patients undergoing surgical extraction of mandibular (jaw) third molars.

Who can participate?
Patients aged 18 years and over who attended dental clinics to extract mandibular third molars

What does the study involve?
Patients were randomly allocated to one of the two study groups. Group 1 subjects (test group) were given a 50% solution of Acacia nilotica mouthrinse while group 2 (control) were given a saline water mouthrinse (placebo). After surgical extraction, both groups were instructed to rinse with 10 ml of their designated mouthrinse twice a day for 7 days, with instructions to start using it after 24 hours for 60 seconds after toothbrushing. Wound healing, edema (swelling), trismus, and pain were evaluated after days 3 and 7.

What are the possible benefits and risks of participating?
The expected benefits of this study are to improve postoperative wound healing and by extension it may aid in the prevention of alveolar osteitis.
No harmful side effects are expected as gum acacia is used as a food additive and is considered Generally Recognized As Safe or GRAS under the Food and Drug Administration’s code of federal regulations. Gum acacia is permitted for use under the Good Manufacturing Practices in the United States, in the Middle East, Europe, and West Africa. The FDA agreed that acacia gum has physiological effects beneficial to human health, such as the reduction of blood glucose and

insulin levels after it is eaten with a meal containing a carbohydrate that raises blood glucose levels.

Where is the study run from?
Dental Clinics of the College of Dentistry, King Khalid University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
September 2023 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mashail Hamid, mhamid@kku.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

The efficacy of acacia nilotica extract on the prevention of alveolar osteitis after impacted lower third molar surgery: a randomized controlled trial

Study objectives
Acacia nilotica extract is effective in reducing post-operative complications in third molar surgery

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2023, The Research Ethics Committee, College of Dentistry, King Khalid University (King Khalid University, Abha, Abha, 61421, Saudi Arabia; +966 (0)172418005; src-cod@kku.edu.sa), ref: IRB/KKUCOD/ETH/2023-24/004

Study design
Single-center randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
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
Prevention of postoperative complications after extraction of impacted lower third molars

Interventions
Method of randomization:
Systematic allocation was used (alternate allocation based on the patient’s presence at the dental clinic).

Patients with impacted lower third molars with a moderate difficulty index were randomly allocated into one of the two study groups. Group 1 subjects (test group) were given a 50% solution of Acacia nilotica mouth rinse while group 2 (control) were given a saline water mouthrinse (placebo). After surgical extraction, both groups were instructed to rinse with 10 ml of their designated mouth rinse twice a day for 7 days, with instructions to start using it after 24 hours for 60 seconds after toothbrushing. Wound healing, edema, trismus, and pain were evaluated after days 3 and 7.

Intervention Type
Other

Primary outcome measure
1. Pain measured using a visual analog scale, ranging from 0 (“no pain”) to 10 (“unbearable pain”) at 9 pm for 7 consecutive days
2. Trismus evaluated using a Vernier gauge to measure the interincisal distance between the right upper and lower central incisors at day 1, 3 and 7 post-extraction
3. Extraoral swelling measured with a 3-0 silk suture put between tragus and corner of mouth, following the maximal convexity of the cheek, and measured against a ruler at day 1, 3 and 7 post-extraction
4. Wound healing evaluated by checking wound edges, color of mucosa and wound closure at day 7 post-intervention after suture removal

Secondary outcome measures
Signs of other postoperative complications, such as postoperative infection and pus discharge

Overall study start date
30/09/2023

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adult patients (aged 18 years and above)
2. Referred to extract their impacted lower third molars with a moderate difficulty index (scores between 5 and 6) according to the Pederson scale

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
40

Total final enrolment
19

Key exclusion criteria

1. History of sensitivity to Acacia Nilotica
2. Uncontrolled systemic diseases
3. History of malignancy or irradiation to the site of extraction
4. History of antibiotics, corticosteroids, anticoagulants, and contraceptive drugs use over the past month
5. Smokers
6. Pregnant or breastfeeding mothers
7. Uncontrolled infection at the site of extraction

Date of first enrolment
01/10/2023

Date of final enrolment
24/12/2023

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Khalid University
Abha
Saudi Arabia
61421

Sponsor information

Organisation
King Khalid University

Sponsor details
Abha
Abha
Saudi Arabia
61421

Sponsor type
Hospital/treatment centre

Website
https://www.kku.edu.sa/en

ROR
https://ror.org/052kwzs30

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/05/2025

Individual participant data (IPD) sharing plan
The dataset generated and/or analysed during the current study will be available upon request from Dr Mashail Hamid (mhamid@kku.edu.sa).

IPD sharing plan summary
Available on request