ISRCTN60510450 https://doi.org/10.1186/ISRCTN60510450

Effectiveness of green tea extract in preventing postoperative bleeding after dental extraction of mandibular molars

Submission date
02/11/2023

Recruitment status
No longer recruiting

Registration date
07/11/2023

Overall study status
Completed

Last Edited
08/04/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Post-extraction bleeding is a common complication after tooth extraction. The aim of this study is to investigate the effectiveness of different green tea extracts in reducing postoperative bleeding after the extraction of mandibular (lower jaw) molars.

Who can participate?
Patients aged 18 years and over attending dental clinics for extraction of lower molars

What does the study involve?
Patients are equally divided into four groups. In the first group, normal saline-soaked sterile gauze is used after tooth extraction while in the other three groups different green tea extracts (GTEs) are applied: in the second group methanolic GTE, in the third group aqueous GTE, and finally tannin in the fourth group. Bleeding is monitored every 5 minutes until bleeding stops and one hour after that.

What are the possible benefits and risks of participating?
Benefits include less bleeding after extraction and less possibility of complications. There are no risks as green tea is considered safe and the maximum dose is not exceeded.

Where is the study run from?
King Khalid University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
September 2022 to February 2023

Who is funding the study?
Investigator initiated and funded

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

Contact information

Type(s)
Principal Investigator

Contact name
Dr Mashail Hamid

ORCID ID
http://orcid.org/0000-0002-7743-1816

Contact details
King Khalid University, Abha, KSA
Abha
Saudi Arabia
61421
+966 (0)555967705
3961181@myuwc.ac.za

Type(s)
Public, Scientific

Contact name
Dr Malaz Mustafa

ORCID ID
http://orcid.org/0000-0001-6642-4621

Contact details
King Khalid University
Abha
Saudi Arabia
61421
+966 (0)553723498
mmmostafa@kku.edu.sa

Type(s)
Scientific

Contact name
Dr Samuel Udeabor

ORCID ID
http://orcid.org/0000-0002-0217-8270

Contact details
King Khalid University
Abha
Saudi Arabia
61421

+966 (0)534771942
seudeabor@kku.edu.sa

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of green tea extract as a local hemostatic agent after dental extraction of mandibular molars: a randomized clinical trial

Study objectives
Green tea extract is effective in reducing post-extraction bleeding when compared to standard methods.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/10/2022, Institutional Review Board, College of Dentistry, King Khalid University (King Khalid University, Abha, 61421, Saudi Arabia; N/A; src-cod@kku.edu.sa), ref: IRB/KKUCOD /ETH/2022-23/021

Study design
Randomized controlled 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
Post-extraction bleeding

Interventions
Patients who were referred for extraction of mandibular molars at King Khalid University College of Dentistry clinics were selected and equally divided into the control and test groups (four groups).

Randomization: 32 pieces of paper numbered from 1-4 were prepared to be used for the male patients and another 32 pieces for the females. Patients were asked to choose a numbered piece of paper (either 1, 2, 3, or 4) and accordingly, he/she received the corresponding intervention. Both patients and the principal investigator were blinded to the type of solution used.

In the first group, normal saline-soaked sterile gauze was used after tooth extraction while in the three test groups, different Green Tea Extracts (GTEs) were applied, in the second group, methanolic GTE, in the third group, aqueous GTE and finally tannin in the fourth group. Monitoring of bleeding was performed every 5 minutes until cessation of bleeding and 1 hour after that. The results were compared using the Krushkal Wallis test, the Chi-Square test, and the Mann Whitney U test.

Intervention Type
Other

Primary outcome measure
Post-extraction bleeding measured by checking the socket every 5 minutes by the principal investigator over 1 hour; after that patient was asked over the phone whether the bleeding continued or not

Secondary outcome measures
Post-extraction complications, measured by contacting patients by phone and asking about any complications on the same day of extraction and the following 3 days

Overall study start date
01/09/2022

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Willingness to participate in the study
3. Referred for extraction of mandibular molar

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
60

Total final enrolment
66

Key exclusion criteria
1. Patients who have sensitivity to green tea
2. Patients who have a clotting disorder or liver disease
3. Patients who have an uncontrolled infection at the site of extraction
4. Patients with a history of malignancy or radiation at the site of extraction
5. Patients who have used antibiotics, corticosteroids, anticoagulants, and contraceptive drugs over the past month
6. Patients who are smokers
7. Patients with comorbidities (hypertension or diabetes)

Date of first enrolment
01/11/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Khalid University
Abha
Abha
Saudi Arabia
61421

Sponsor information

Organisation
King Khalid University

Sponsor details
Abha
Abha
Saudi Arabia
61421
+966 (0)17 241 8000
src-cod@kku.edu.sa

Sponsor type
University/education

Website
https://kku.edu.sa

ROR
https://ror.org/046gga527

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The data will be available upon request from Dr Mashail Hamid (mhamid@kku.edu.sa). Shared data will be related to the measured variable, patient age and sex but not identity. It will be

available from the present date up to 3 years (05/11/2023 to 05/11/2026). Signed consents were obtained from patients, and personal patient information (name, telephone no) was required for follow-up after they left the clinic. No ethical or legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2024	08/04/2025	Yes	No