

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/04/2025	Condition category Oral Health	<input type="checkbox"/> 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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Efficacy

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 Kruskal Wallis test, the Chi-Square test, and the Mann Whitney U test.

Intervention Type

Other

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

100 years

Sex

All

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

ROR

<https://ror.org/046gga527>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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