

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparative assessment of the effect of methanolic extracts of green tea and chlorhexidine gel on postoperative pain control following surgical removal of impacted third molars

Protocol summary

Study aim

Comparison of the effect of methanolic extracts of green tea and chlorhexidine gel on postoperative pain control following surgical removal of impacted third molars

Design

In this clinical trial study, there will be 30 person aged 18-40 that are given after third molar surgery, randomly two compounds of chlorhexidine and green tea . Each participant is assigned a code. .

Settings and conduct

Dental wisdom surgery is done by an oral and maxillofacial specialist in a similar process. Patients are trained to use chlorhexidine or green tea gel twice a day for one week. Choosing a gel type will be random and the participants will not be aware of the type of substance. VAS is used to record the level of pain.

Participants/Inclusion and exclusion criteria

The entering criteria including the person 18-40 years old that have two impacted third molar in mandible and have not the Hemorrhagic disorders , systemic diseases and acute and uncontrolled infection in the surgical ward the exclusion criteria including Pregnant or lactating people and The presence of lesion in the area of surgery in radiography.

Intervention groups

Chlorhexidine, Green Tea

Main outcome variables

Postoperative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171020036896N7**

Registration date: **2018-12-21, 1397/09/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

Registration date

2018-12-21, 1397/09/30

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32119023

Email address

sajadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of the effect of methanolic extracts of green tea and chlorhexidine gel on postoperative pain control following surgical removal of impacted third molars

Public title

the effect of methanolic extracts of green tea and chlorhexidine gel on postoperative pain control

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Existence of tow impacted third molar in mandible
The absence of Hemorrhagic disorders and systemic diseases
The absence of acute and uncontrolled infection in the surgical ward

Exclusion criteria:
Smokers
Pregnant or lactating people
The presence of lesion in the area of surgery in radiography

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Two impacted wisdom teeth in each person's mandible

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization or unrestricted method will be used and randomization unit is Individual .we will use from Roll of a die from the methods of simple randomization because there are 2 agent in this study that actually the tool of randomization is dice. So the numbers 1 and 2 are for the first agent(chlorhexidine) 3 and 4 for the second agent (green tea) . The next step Allocation concealment will be done, In such a way that the allocated group is not known before the assignment of the individual. To achieve this goal, a non-transparent, sealed, random sequence envelope is used . In this way, the statistical specialist will provide 30envelopes and each of the randomly generated links will be recorded on a card and the cards are arranged in the envelopes . In order to maintain a random sequence, the numbering of envelopes on the outer surface is done in the same order. Finally, the envelops are enclosed and placed in the box, respectively. At the time of the implementation of the study, according to the order of entry of eligible participants, one of the envelopes is opened respectively and will determine the group assigned to that participant. In this study, the assistant of Pediatric Dentistry examines the participants in terms of inclusion and exclusion criteria. Randomization methods are done by an statistical specialist and performance of the study is done by a trained dental student.

Blinding (investigator's opinion)
Double blinded

Blinding description
Because all two materials are in the same consistency gel, in a uniform shape and color, considering the informed consent, participants are unaware of material. Data analyzer, is also unaware of the groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethic Committee of kerman University of Medical Sciencess

Street address
Vice-Chancellor for Research, Building of Kerman University of Medical Sciences, Tahmasbabad cross, Jihad Street

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2018-09-30, 1397/07/08

Ethics committee reference number
IR.KMU.REC.1397.240

Health conditions studied

1

Description of health condition studied
The level of postoperative pain of impacted third molar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The level of postoperative pain of impacted third molar

Timepoint
One week

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The two cc methanolic extract of green tea 20 % is applied twice a day for one week after surgery of the impacted wisdom teeth by the patient on the surgical site.

Category

Treatment - Drugs

2**Description**

Control group: The two cc chlorhexidine 2 % is applied twice a day for one week after surgery of the impacted wisdom teeth by the patient on the surgical site.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kerman Faculty of Dentistry

Full name of responsible person

Dr Fatemeh sadat Sajadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

60

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Sajadi

Position

Associate Professor of Pediatric Dentistry

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available