

# 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, Jahad 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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Department of Maxillofacial Surgery ,School of Dentistry,Shafa street

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

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Abbas Pardakhti

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Tahmasebabad Crossing, Deputy of Research and Technology University

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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 scientific inquiries****Contact****Name of organization / entity**

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**Position**

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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