Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of green tea mouthwash with normal saline on swelling and pain caused by impacted wisdom tooth surgery in patients

Protocol summary

Study aim
Comparing the effect of green tea mouthwash with normal saline on swelling and pain caused by wisdom teeth surgery in patients

Design
Clinical trial with an intervention group and a control group, with parallel groups, double-blind, randomized, phase 2 on 24 patients.

Settings and conduct
Candidate patients for wisdom tooth surgery who refer to the surgical department of Shiraz Dental School during the study, if they are eligible, will be included in the study and will be randomly assigned to the intervention and control groups using the random block method. This study will be done in a double-blind manner. In such a way that the patients and the person checking the results and the person analyzing the data will not know about the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with similarly impacted third molar teeth, age 20 to 35 years, no systemic disease, no TMJ problems and no mouth opening restrictions, non-smokers, no pregnancy. Exclusion criteria: non-cooperation of the patient.

Intervention groups
Intervention group: Green tea mouthwash is made by Irsha company. The surgeon removes the mouthwash label and adds green apple flavoring to it. The intervention period is one week. After the surgery, mouthwash is started. Mouthwash is used 4 times a day. Every time, 20 ml of mouthwash is swirled in the mouth for 30 seconds. Control group: The normal saline mouthwash used is made in Irsha company. The surgeon removes the mouthwash label and adds green apple flavoring to it. The intervention period is one week. After the surgery, mouthwash is started. Mouthwash is used 4 times a day. Every time, 20 ml of mouthwash is swirled in the mouth for 30 seconds.

Main outcome variables
pain and swelling

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220608055108N1**
Registration date: **2023-01-03, 1401/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-03, 1401/10/13**
Update count: **0**

Registration date
2023-01-03, 1401/10/13

Registrant information
Name
SHILA SHAHSAVARI POUR
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3626 3193
Email address
shahsavari_sh@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of green tea mouthwash with normal saline on swelling and pain caused by impacted wisdom tooth surgery in patients

Public title
Comparison of the effect of green tea mouthwash with normal saline on the complications of impacted wisdom tooth surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with impacted third molars similarly in terms of occlusion Age 20 to 35 years No systemic disease No Temporomandibular joint problems and no mouth opening restrictions Non-smoker No pregnancy
Exclusion criteria:
Patient non-cooperation

Age
From **20 years** old to **35 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Quadruple blocks including two allocations for the intervention group and two allocations for the control group are considered. Six possible modes of permuting treatments are listed and each is written on a card. Each time a block will be selected and the sequence of treatment will be registered until the treatment allocations become completed for all 24 participants. The randomization was performed by a methodologist. Allocation concealment will be done by the main researcher. On each card a sequence will be written and sealed. Pockets will be put in a box. A pocket will be allocated for each participant based on order of enrollment.

Blinding (investigator's opinion)
Double blinded

Blinding description
The professor of surgery department is the one who performs wisdom tooth surgery. He writes down what mouthwash he has prescribed for each patient. Patients of both participating groups are treated with a certain dose of painkillers and antibiotics. In both intervention and control groups, green apple flavoring is added to the mouthwash so that the patients are blinded. The student is responsible for measuring the results. A statistician analyzes the data. The student and the statistician are blinded to the type of mouthwash prescribed for the patients. Since the outcome analyzer will be different from the one who prescribed the mouthwashes, the outcome assessor will be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz Faculty of Dentistry Ethics Committee
Street address
Shiraz Dental School .,corner of Mehr St., Qasrdasht St., Shiraz
City
shiraz
Province
Fars
Postal code
7195615878

Approval date
2022-06-22, 1401/04/01

Ethics committee reference number
IR.SUMS.DENTAL.REC.1401.032

Health conditions studied

1

Description of health condition studied
Implanted wisdom tooth surgery

ICD-10 code
Z98.818

ICD-10 code description
Other dental procedure status

Primary outcomes

1

Description
pain

Timepoint
Before intervention: one day after surgery. After intervention: one week after surgery.

Method of measurement
Pain: According to the patient's measurement is measured by visual analog scale index. In this way, the patient is asked to rate his pain from 1 to 10, where 1 is the lowest pain and 10 is severe.

2

Description
swelling
Timepoint
We measure the patient's swelling one day after the surgery, which is before the intervention, and one week after the intervention.
Method of measurement
Swelling: The distance from the ear tragus to the nasal alar, the ear tragus to the angle of the mandible, the angle of the mandible to the alar of the nose, will be measured by a caliper before surgery.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Green tea mouthwash is made by Irsha company. The surgeon removes the mouthwash label and adds green apple flavoring to it. The intervention period is one week. After the surgery, mouthwash is started. Mouthwash is used 4 times a day. Every time, 20 ml of mouthwash is swirled in the mouth for 30 seconds. How to use is explained to the patient orally and in writing. Complications after wisdom tooth surgery appear in the first week after the surgery, and we intend to check the effect of green tea mouthwash on the recovery process by checking on the 1st, 3rd and 7th days.
Category
Treatment - Drugs

2

Description
Control group: The normal saline mouthwash used is made in Irsha company . The surgeon removes the mouthwash label and adds green apple flavoring to it. The intervention period is one week. After the surgery, mouthwash is started. Mouthwash is used 4 times a day. Every time, 20 ml of mouthwash is swirled in the mouth for 30 seconds. How to use is explained to the patient orally and in writing. Complications after wisdom tooth surgery appear in the first week after the surgery, and we intend to check the effect of green tea mouthwash on the recovery process by checking on the 1st, 3rd and 7th days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Oral and Maxillofacial Surgery, Shiraz Dental School
Full name of responsible person
Shila Shahsavari pour
Street address
Shiraz Dental School .,corner of Mehr St., Qasrdasht St., Shiraz
City
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Fars
Postal code
7195615878
Phone
+98 71 3626 3193
Email
shahsavari_sh@sums.ac.ir
Web page address
https://dental.sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
Street address
Shiraz university of Medical Sciences, Zand street, Iran
City
shiraz
Province
Fars
Postal code
7186782559
Phone
+98 71 3212 2438
Email
memarpourm@sums.ac.ir
Web page address
https://www.sums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
Shiraz University of Medical Sciences
Full name of responsible person
Shila Shahsavari pour
Position
Consultant
Latest degree
Subspecialist
Other areas of specialty/work
Dentistry
Street address
Shiraz Dental School .,corner of Mehr St., Qasrdasht St., Shiraz
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Shila Shahsavari pour
Position
Consultant
Latest degree
Subspecialist
Other areas of specialty/work
Dentistry
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Email
shahsavari_sh@sums.ac.ir
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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Shila Shahsavari pour
Position
Consultant
Latest degree
Subspecialist
Other areas of specialty/work
Dentistry
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Email
shahsavari_sh@sums.ac.ir
Web page address
https://dental.sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected data will be shared after deidentification of participants.
When the data will become available and for how long
The data can be accessed 2 months after the results are published in the international journal.
To whom data/document is available
Students, professors and researchers of companies active in the mouthwash industry
Under which criteria data/document could be used
By citing the source and with a commitment not to disclose individuals privately
From where data/document is obtainable
Refer to dental.sums.ac.ir .
What processes are involved for a request to access data/document
The researchers in academic institutions can send email to responsible person and request information.
Comments