

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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**

Shiraz

##### **Province**

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**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Shila Shahsavari pour

**Position**

Consultant

**Latest degree**

Subspecialist

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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**

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## 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](https://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**

