

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of combined herbal mouthwash (containing Thymus, Myrtus, Glycyrrhiza and Aloe Vera) on postoperation complications of mandibular impacted third molar; A randomized triple-blind clinical trial study

#### Protocol summary

##### Study aim

Evaluation of the effect of combined herbal mouthwash (containing Thymus, Myrtus, Glycyrrhiza, and Aloe Vera) on post-operation complications of mandibular impacted third molar

##### Design

A triple blinded clinical trial with a control group, with parallel groups, randomized by a random table of numbers, phase 3, on 60 patients in two groups of 30.

##### Settings and conduct

Patients come to Qazvin Dental School at their appointment, and after the surgery, they use their respective coded mouthwash, which the patient, the examiner, and the statistical consultant don't know about its contents. After the surgery, the patients are asked to use 10 ml of the contents of their coded container, which contains herbal combined mouthwash or placebo, for 30 sec. and continue twice a day for 2 weeks. And on the 3, 7, and 14 days, refer to us for follow-up.

##### Participants/Inclusion and exclusion criteria

In this study, patients in the age range of 20-60 who needed mandibular 3rd molar surgery with the same difficult conditions are selected. After providing explanations of the method of implementation and the purpose, eligible patients with full personal consent enter the study. Inclusion criteria: Willingness and satisfaction of the patient to participate The presence of unilateral or bilateral mandibular 3rd molar Possessing a panoramic radiograph photo prepared in the last 6 months Absence of any systemic disease Not taking medicine, smoking, alcohol, and drugs Absence of pregnancy and breastfeeding Exclusion criteria: Lack of proper patient cooperation Patient's lack of satisfaction to continue the study Getting a specific disease Occurrence of pregnancy Occurrence of complications during surgery

##### Intervention groups

Intervention group: recipient of herbal mouthwash (hymus, Myrtus, Glycyrrhiza, and Aloe Vera) Control group: receiving placebo (normal saline)

##### Main outcome variables

Swelling Trismus Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220522054965N1**

Registration date: **2022-08-20, 1401/05/29**

Registration timing: **prospective**

Last update: **2022-08-20, 1401/05/29**

Update count: **0**

##### Registration date

2022-08-20, 1401/05/29

##### Registrant information

##### Name

Muhammad Reza Asgari Ghonche

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3369 1527

##### Email address

m.asgari77@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-09, 1401/06/18

**Expected recruitment end date**

2023-09-21, 1402/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of combined herbal mouthwash (containing Thymus, Myrtus, Glycyrrhiza and Aloe Vera) on postoperation complications of mandibular impacted third molar; A randomized triple-blind clinical trial study

**Public title**

Evaluation of the effect of combined herbal mouthwash (containing Thymus, Myrtus, Glycyrrhiza and Aloe Vera) on the complications of mandibular wisdom tooth surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness and satisfaction of the patient to participate in the study The presence of unilateral or bilateral mandibular wisdom teeth Possessing a panoramic radiograph with high quality and prepared in the last 6 months age between 20-60

**Exclusion criteria:**

Lack of proper cooperation and consent of the patient to participate in the study Suffering from systemic diseases Taking medicine, smoking, alcohol and drugs Pregnancy and breastfeeding in women

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple individual randomization, by the table of random numbers: Tables of random numbers are prepared by computers that arrange numbers randomly in both row and column directions. For use, the researcher must first determine the exact number of people in the study Then, to select the sample people from the table, he randomly starts from a point of the table in the direction of the row or column, and he can choose the point by closing his eyes and placing his finger or the tip of the pen on the table. This work should continue until the number of sample people can be selected.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, the patient, examiner or clinical caregiver and statistical consultant are blind to the study groups. Blinding is done by assigning codes A and B to two groups and equating the shape of the mouthwash bottle and its content.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Qazvin University of Medical Sciences

**Street address**

Shahid Beheshti Blvd

**City**

Qazvin

**Province**

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**Postal code**

3414847464

**Approval date**

2022-08-03, 1401/05/12

**Ethics committee reference number**

IR.QUMS.REC.1401.128

**Health conditions studied****1****Description of health condition studied**

Complications of impacted third molar surgery

**ICD-10 code**

K01.1

**ICD-10 code description**

Impacted teeth

**Primary outcomes****1****Description**

Swelling

**Timepoint**

Before and after surgery, the third day, the seventh day, the fourteenth day

**Method of measurement**

Ruler with millimeter scale

## 2

### **Description**

Trismus

### **Timepoint**

Before and after surgery, the third day, the seventh day, the fourteenth day

### **Method of measurement**

Ruler with millimeter scale

## 3

### **Description**

Pain

### **Timepoint**

Before and after surgery, the third day, the seventh day, the fourteenth day

### **Method of measurement**

Visual Analogue Scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: 280 ml combined herbal mouthwash bottle (containing 1% extract from each four plants: Thymus, Myrtus, Glycyrrhiza and Aloe Vera) - how to use: 10 ml each time - 30 seconds - twice a day - for two weeks

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: 280 ml normal saline mouthwash bottle - how to use: 10 ml each time - 30 seconds - twice a day - for two weeks

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Qazvin Faculty of Dentistry, Department of Oral and Maxillofacial Surgery

##### **Full name of responsible person**

Muhammad Reza Asgari Ghonche

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Shahid Bahonar Blvd

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##### **Phone**

+98 28 3335 3061

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dentfaculty@qums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Qazvin University of Medical Sciences

##### **Full name of responsible person**

Mahdi Mirhashemi

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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**

Qazvin University of Medical Sciences

#### **Proportion provided by this source**

1

#### **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**

Qazvin University of Medical Sciences

##### **Full name of responsible person**

Muhammad Reza Asgari Ghonche

##### **Position**

General dentistry student

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Mahdieh Zarabadipour  
**Position**  
Specialist of the Faculty of Oral and Maxillofacial Diseases of Qazvin Dental Faculty  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Muhammad Reza Asgari Ghonche  
**Position**  
General dentistry student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry

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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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

Only part of the non-confidential data of the participants will be used and published for research purposes only. For example: age, gender, BMI, etc.

### When the data will become available and for how long

After the end of the study and the publication of the articles derived from it.

### To whom data/document is available

All researchers, students and related people in academic institutions

### Under which criteria data/document could be used

The use of data by mentioning the authors' information and referencing is free.

### From where data/document is obtainable

Correspond author: Muhammad Reza Asgari Ghonche  
Phone number: 09912069209 Email:  
m.asgari77@yahoo.com

### What processes are involved for a request to access data/document

Requests for documentation will be answered as soon as possible, within several days.

### Comments