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

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Iran (Islamic Republic of)

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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
Qazvin
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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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
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
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Person responsible for scientific inquiries

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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