Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Carvacrol gel, and Chlorhexidine in reducing postoperative pain, and dry socket after surgical removal of impacted mandibular third molars- a clinical trial

Protocol summary

Study aim

Comparison of the effect of Carvacrol gel, and Chlorhexidine in reducing postoperative pain, and dry socket after surgical removal of impacted mandibular third molars

Design

Randomized non-blinded clinical trial with 4 parallel group design of 80 patients. Patients will be assigned to the study groups using simple randomization method.

Settings and conduct

This clinical trial will be performed on 80 patients referred to the Oral and Maxillofacial Surgery Department of Tabriz Dental School who are candidates for mandibular third molar surgery. After obtaining the inclusion criteria and obtaining informed and written consent, using simple randomization method, patients will be assigned to the study groups: Group 1: which is the control group Group 2: Wash only before the surgery with chlorhexidine mouthwash Group 3: For this group, after surgery carvacrol gel is placed on the wound site (inside the tooth socket) Group 4: The group receiving carvacrol-free gel (To remove the base effect)

Participants/Inclusion and exclusion criteria

Inclusion criteria: All adult patients (over 18 years old) without any systemic disease Absent history of dry socket Having one or two impacted wisdom teeth (surgery on one side only) The presence of adjacent second molars No antibiotics and anti-inflammatory intake at least 7 days before surgery) Exclusion criteria: Hypersensitivity to local anesthetics History of smoking

Intervention groups

Group I: which is the control group, Group II: Rinse once with chlorhexidine mouthwash pre-operatively, Group III: in which 0.5 % w/w Carvacrol-based gel is placed in the socket after surgical extraction of third molar, Group IV: vehicle gel treated group

Main outcome variables

severity of pain; Occurrence or non-occurrence of dry socket; the number of pain relief tablets taken

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110420006239N4**
Registration date: **2021-08-03, 1400/05/12**
Registration timing: **prospective**

Last update: **2021-08-03, 1400/05/12**
Update count: **0**

Registration date

2021-08-03, 1400/05/12

Registrant information

Name
javad yazdani
Name of organization / entity
faculty of dentistry
Country
Iran (Islamic Republic of)
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+98 41133559659
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yazdanij@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Carvacrol gel, and Chlorhexidine in reducing postoperative pain, and dry socket after surgical removal of impacted mandibular third molars- a clinical trial

Public title
Comparison of the effect of Carvacrol gel, and Chlorhexidine in reducing pain, and dry socket
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All adult patients (over 18 years old) healthy without any systemic disease Absent history of dry socket Having one or two impacted wisdom teeth (surgery on one side only) The presence of adjacent second molars No antibiotics and anti-inflammatory intake at least 7 days before surgery)
Exclusion criteria:
Hypersensitivity to local anesthetics History of smoking
Age
From **18 years** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this trial, simple randomization will be used to achieve four groups with equal sample size. 80 identical envelopes (according to the required number of samples) are prepared and in 20 of them, group one, in 20 of them, group two, in 20 of them, group three, in the other 20, group four are written and the envelopes are sealed. Patients are randomly assiged into one of four groups by selecting an envelope.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical research ethics committee of Tabriz university of medical sciences
Street address
Third Floor, Vice Chancellor for Research and Technology/Tabriz University of Medical Sciences, Central Building No. 2 /Golgasht St./Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-05-17, 1400/02/27
Ethics committee reference number
IR.TBZMED.REC.1400.166

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

2

Description of health condition studied
Dry socket
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Total analgesic drug consumption
ICD-10 code
Y45.3
ICD-10 code description
Other nonsteroidal anti-inflammatory drugs [NSAID]

Primary outcomes

1

Description
Pain
Timepoint
The first, second and seventh days after surgery
Method of measurement
Visual analog scale (asking from patient, scoring from 1 to 10)

2

Description
Dry socket
Timepoint
Seventh day post-operation
Method of measurement
Intraoral examination for signs of dry socket

Secondary outcomes

1

Description
Number of pain relief tablets taken
Timepoint
The first, second and seventh days after surgery
Method of measurement
Asking the patient

Intervention groups

1

Description
Control group: do not receive any kind of mouthwash
Category
N/A

2

Description
Intervention group I: Rinse once with 0.2%chlorhexidine mouthwash pre-operatively
Category
Treatment - Drugs

3

Description
Intervention group II: in which 0.5 % w/w Carvacrol-based gel is placed in the socket after the surgery.
Category
Treatment - Drugs

4

Description
Intervention group III: vehicle gel treated group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz University of Medical Sciences
Full name of responsible person
Javad Yazdani
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Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave.
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Yazdanij@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Samiei
Street address
Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave.
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Postal code
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Phone
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Email
Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Javad Yazdani

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available