

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 41133559659

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yazdani@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 assigned 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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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

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**Contact****Name of organization / entity**

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Position

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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