

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the Effect of Ozonized Water and Normal Saline on Postoperative Pain of Impacted mandibular third molars.

Protocol summary

Study aim

Comparison of the Effect of Ozonized Water with Normal Saline on pain after third Mandibular occult surgery in patients referred to the Department of Oral and Maxillofacial Surgery, Islamic Azad School of Dentistry, Tehran, 2020

Design

Clinical trial with Control group, with Parallel groups, Double-blind, Randomized, phase 3, on 40 patients. Simple random sampling.

Settings and conduct

Samples are randomly selected from the patients referred to the Oral and Maxillofacial Surgery Department of Tehran Azad Dental School. Patients and surgeons are unaware of the type of detergent used on each side. The desired side and the desired material are selected randomly (coins). The researcher is the controller.

Participants/Inclusion and exclusion criteria

People with Mandibular occult Wisdom Teeth Bilateral, do not have Systemic Disease.

Intervention groups

The impacted mandibular wisdom tooth of the mandible is the side that is washed with Ozonated water is the intervention group and the side that is washed with Normal Saline is the control group.

Main outcome variables

The mean amount of Pain after latent Third Molar Surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210119050080N1**

Registration date: **2021-02-07, 1399/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-07, 1399/11/19**

Update count: **0**

Registration date

2021-02-07, 1399/11/19

Registrant information

Name

Eshagh Lasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

elasemi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Ozonized Water and Normal Saline on Postoperative Pain of Impacted mandibular third molars.

Public title

Evaluation of the Effect of Ozonized Water and Normal Saline on Pain after Impacted Wisdom Tooth Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

People with Mandibular Wisdom Teeth are Bilateral

Exclusion criteria:

No systemic disease

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Bilateral Wisdom Teeth of the Mandible

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization Method

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and Surgeon do not know what detergent is used on each side of the surgery. The syringes contain two solutions are similar, that are provided to the surgeon by the researcher.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of the School of Dentistry, Tehran
Azad University of Medical Sciences

Street address

No.9, Neyestan9 Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-09-30, 1399/07/09

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.184

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

Pain after Wisdom Tooth Surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain score in the visual analogue scale questionnaire

Timepoint

24-48-72 hours, day 5 and day 7 after surgery

Method of measurement

Using pain visual analogue scale questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Ozonized water is produced with an ozone generator model OZONEDS5 is produced by Nab zist Company with a concentration of 11-12 micrograms per ml. The surgical site is washed with this solution.

Category

Prevention

2**Description**

Control group: 0.9% sodium chloride solution (9 g NaCl per liter of water) from Iran Injection and Pharmaceutical Products Company is used to wash the surgical site.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Surgery, Faculty of Dentistry, Islamic
Azad University of Tehran

Full name of responsible person

Dr Eshagh Lasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Arash Azizi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

None applicable

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Dr Eshagh Lasemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

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Latest degree

Medical doctor

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Fax

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

A part of the information, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

The start of the access period will be 6 to 12 months after the results are released.

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data will be available for access to dental research centers, universities and public and private health centers.

From where data/document is obtainable

Applicants can contact the person responsible for the article to receive the information. Dr Eshagh Lasemi, elasemi@yahoo.com 00989123871430 No9, Neistan9 Ave, Pasdaran Ave, Tehran, samaneh Rahimi, Dr.samanehrahimi.m@gmail.com

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

Demand by email to the person responsible for the article Dr.Eshaq.Lasemi.elasemi@yahoo.com

Comments