# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 Ẽshagh Lasemi

**Street address**
No.9, neiestan9 Ave, pasdaran Ave

**City**
Tehran

**Province**
Tehran

**Postal code**

91946853314

**Phone**
+98 21 2676 2270

**Email**
elasemi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Islamic Azad University

**Full name of responsible person**
Dr Arash Azizi

**Street address**
No.9, neiestan9 Ave, pasdaran Ave

**City**
Tehran

**Province**
Tehran

**Postal code**
1946853314

**Phone**
+98 21 2676 2270

**Email**
elasemi@yahoo.com

**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

**Street address**
No. 9, Neiestan 9 Ave, Pasdaran Ave

**City**
Tehran

**Province**
Tehran

**Postal code**
1946853314

**Phone**
+98 21 2676 2270

**Email**
elasemi@gmail.com

## Person responsible for scientific 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

**Street address**
No.9, Neiestan9 Ave, Pasdaran Ave

**City**
Tehran

**Province**
Tehran

**Postal code**
1946853314

**Phone**
+98 21 2676 2270

**Email**
Dr.samanehrahimi.m@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Islamic Azad University

**Full name of responsible person**
Eshagh Lasemi

**Position**
Associate professor

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dentistry

**Street address**
No. 9, Neiestan 9 Ave, Pasdaran Ave

**City**
Tehran

**Province**
Tehran

**Postal code**
1946853314

**Phone**
+98 21 2676 2270

**Fax**

**Email**

elasemi@gmail.com

## 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 to12 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**
Ḍemand by email to the person responsible for the article Dr.Eshaq Lasemi.elasemi@yahoo.com

**Comments**