

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effects of ozonated water in non-surgical patients with chronic periodontitis

Protocol summary

Study aim

Evaluation the effect of using ozonated water in non-surgical treatment of patients with chronic periodontitis

Design

Trial study(Phase 2) with parallel groups and design of a double-blind clinical trial design on 30 patients

Settings and conduct

This study is being done on patients referred to the periodontal department of Babol dental school. First, a clinician randomly divides the patients into two groups. Clinical parameters are measured by the second clinician (blind) and scaling is performed by the third clinician (blind). Parameter re-measurement is also performed by the second clinician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mild to moderate chronic periodontitis
Patient with o'leary plaque index equal or less than 20
Exclusion criteria: Smoking

Intervention groups

The intervention group receives scaling and root planing (SRP) with ozonated-water. SRP includes full debridement of supragingival and subgingival plaque performed using a DTE D7 ultrasonic device. Full SRP is performed in two sessions of 40 minutes long each with a one-week interval in between the sessions. Each patient is followed up in four and eight weeks after the second treatment session. In each follow-up visit, the patient's clinical periodontal status is evaluated by periodontal pocket depth (PPD), clinical attachment level (CAL) and gingival index (GI). Patients in the control group receive scaling and root planing (SRP) with tap water(placebo).

Main outcome variables

Periodontal pocket depth (PPD); Clinical attachment loss (CAL); Gingival index (GI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090311001760N48**

Registration date: **2019-09-17, 1398/06/26**

Registration timing: **retrospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **0**

Registration date

2019-09-17, 1398/06/26

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-11, 1398/05/20

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of ozonated water in non-

surgical patients with chronic periodontitis

Public title

Effect of ozonated water in scaling and root planing

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Range age of 20-70 years Mild to moderate chronic periodontitis Patient with o'leary plaque index equal or less than 20

Exclusion criteria:

Smoking Pregnancy and Lactation Any types of systemic disease like hyperthyroidism, severe anemia, severe myasthenia, acute alcohol poisoning, recent myocardial infarction, active bleeding, etc. Patients who received surgical or non-surgical or antibiotic therapies over the past 6 months. People who should not use ultrasonic devices, including people who has infectious diseases and immune deficiency, those at risk of respiratory diseases.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The first clinician assigns patients randomly to control and intervention groups. The second clinician which is blind toward the treatment, evaluates the clinical parameters. Scaling and root planing procedures are performed by a third clinician, who is blind regarding whether ozonated water or tap water is being used. The follow-up visits are performed by the second clinician, too.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj Afrouz St.

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Babol

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Mazandaran

Postal code

4717647745

Approval date

2018-04-23, 1397/02/03

Ethics committee reference number

IR.MUBABOL.REC.1397.014

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

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes**1****Description**

Periodontal pocket depth

Timepoint

baseline, 4 and 8 week after scaling and root planing (SRP)

Method of measurement

William's periodontal probe

2**Description**

Clinical attachment loss

Timepoint

baseline, 4 and 8 week after SRP

Method of measurement

William's periodontal probe

3**Description**

Gingival index

Timepoint

baseline, 4 and 8 week after SRP

Method of measurement

William's periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group receives scaling and root planing (SRP) with ozonated-water. SRP includes full debridement of supragingival and subgingival plaque performed using a DTE D7 ultrasonic device (Made in IR. Iran. by Ozonsazan Pasargad corporation. SS8 Ozone generator). Full SRP is performed in two sessions of 40 minutes long each with a one-week interval in between the sessions. The DTE D7 ultrasonic device consists of a water tank filled with ozonated-water. Based on the half-life of ozone molecules in water, the water tanks are refilled with fresh ozonated-water after 20 minutes. The maximum safe concentration of ozone in water, based on previous studies, is 8 ppm, and its proper concentration in different dentistry treatments, including periodontal non-surgical ones, 1.5 ppm. After the procedure, patients are instructed properly to adhere to oral and dental hygiene. Each patient is followed up in four and eight weeks after the second treatment session. In each follow-up visit, the patient's clinical periodontal status is evaluated by periodontal pocket depth (PPD), clinical attachment level (CAL) and gingival index (GI).

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group receive scaling and root planing (SRP) with tap water. SRP included full debridement of supragingival and subgingival plaque performed using a DTE D7 ultrasonic device. Full SRP is performed in two sessions of 40 minutes long each with a one-week interval in between the sessions. The DTE D7 ultrasonic device with a water tank that is filled with tap water. To ensure that the methods that are used for patients of the control group are seemingly equivocal to those of the intervention group, the water tank is refilled with tap water after 20 minutes, too.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Babol University of Medical Sciences

Full name of responsible person

Mojan Ghafouri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mojan Ghaforui

Position

Dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mohadese Yazdanpanah

Position

Periodontist/Assistant Professor of Faculty of Dentistry

Latest degree

Specialist

Other areas of specialty/work

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Position

MA

Latest degree

Master

Other areas of specialty/work

Others

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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