Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Province
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
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Full name of responsible person
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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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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