Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of oral irrigator on periodontal indices in patients with generalized gingivitis

Protocol summary

Study aim
Study and comparison between effect of oral irrigator and dental floss as supplement of toothbrush on periodontal index at patients with gingivitis.

Design
Clinical trial with control group and parallel groups, single blind, randomized, phase 2 and 3 groups on 40 patients. A randomized table of numbers was used for randomization.

Settings and conduct
The study is located in periodontology department of Mashhad Dental School. In the intervention group, each participant will be given an oral irrigator(waterjet) and a toothbrush to compare the effect of waterjet on reducing gingival index, plaque index and bleeding on probe after 14 and 28 days. In the control group, each participant will be given toothbrushes and floss and after 14 and 28 days, we will measure the mentioned indicators. In this study, blinding was performed by using closed envelopes. The outcome stabilizer is not aware of the intervention method in the groups.

Participants/Inclusion and exclusion criteria
1.Generalized gingivitis. 2.Gingival index(Loe and Sillness Gingival Index) 1 or more. 3.Bleeding on probing at more than 10 percent of teeth. 4.Participant not affected by systemic diseases associated with periodontal conditions. 5.Not pregnancy. 6.The patients without periodontal treatments within 1 month ago.

Intervention groups
In the intervention group, each participant will be given an oral irrigator(waterjet) and a toothbrush to compare the effect of waterjet on reducing gingival index, plaque index and bleeding on probing after 14 and 28 days. In the control group, each participant will be given toothbrushes and floss and after 14 and 28 days, we will measure the mentioned indicators.

Main outcome variables
Gingivitis; Plaque index; Oral health

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211221053478N1**
Registration date: **2022-07-27, 1401/05/05**
Registration timing: **prospective**

Last update: **2022-07-27, 1401/05/05**
Update count: **0**

Registration date
2022-07-27, 1401/05/05

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-08-12, 1401/05/21
Expected recruitment end date
2022-09-12, 1401/06/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of oral irrigator on periodontal indices in patients with generalized gingivitis

Public title
The effect of oral irrigator on patients with gingival inflammation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Generalized gingivitis Gingival index(Loe and Sillness Gingival Index) 1 or more Bleeding on probing at more than 10 percent of teeth
Exclusion criteria:
Pregnancy The patients under periodontal treatments within 1 month ago Systemic diseases associated with periodontal conditions
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were randomly assigned to the intervention and control groups by block randomization using a table of random numbers. Sealed envelop were used for allocation of random numbers to the patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patients could not be blinded to the allocated procedure. However, the examiner who examine the plaque index, gingival index and bleeding on probing after the intervention was blinded to the group allocation of patients. Thus, the study had a single-blinded design. The statistician who analyzed the data was also blinded to the group allocation of patients.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Science
Street address
Beginning of Vakilabad Ave., In front of Mellat Park ., Mashhad Town
City
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Province
Razavi Khorasan
Postal code
9177948959
Approval date
2021-12-01, 1400/09/10
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1400.118

Health conditions studied

1

Description of health condition studied
Gingivitis
ICD-10 code
K05.10
ICD-10 code description
Chronic gingivitis, plaque induced

Primary outcomes

1

Description
Percentage of people with gingival index 1 or higher
Timepoint
Measurement of gingival index at the beginning of the study and 14 and 28 days after starting using dental floss and waterjet.
Method of measurement
Clinical examination and direct observation of gingival changes.

Secondary outcomes

1

Description
Bleeding on probing in more than 10 percent of teeth
Timepoint
Measurement of Bleeding on probing at the beginning of the study and 14 and 28 days after starting using dental floss and waterjet.
Method of measurement
Using the periodontal Williams probe

2

Description
Generalized or localized gingivitis.
Timepoint
Evaluation of gingivitis at the beginning of the study and 14 and 28 days after starting the use of dental floss and waterjet.
Method of measurement

Clinical examination and direct observation of gingival changes.

Intervention groups

1

Description
Control group: After scaling patients' teeth, flossing (Mina brand) will be done twice a day for 4 weeks after brushing by people in the control group. Brushing will be done by Modified bass method and twice a day by Hi Dent brand manual toothbrush. The correct method of brushing and using dental floss will be taught by a trained evaluator.

Category
Treatment - Devices

2

Description
Intervention group: Oral irrigator will be used after brushing in the intervention group. The duration of using the device is twice a day for 4 weeks. Brushing will be done by Modified bass method and twice a day by Hi Dent brand manual toothbrush. The correct method of brushing and using oral irrigator will be taught by a trained dental student. Oral irrigator under the registered name (Waterjet mouth washer with the ability to monitor and control the user's hygienic behavior) has been designed and patented by a private Iranian company (registration number: 72641) (patent number: 103383). Unlike other existing devices based on mechanical mechanisms and piston performance, this device has been designed and manufactured based on electromechanical system and on centrifuge performance. The power of spraying system is between 10 to 70 psi and beats from 100 to 1000 times per minute according to microcontroller programming. The liquid used in the oral irrigator is distilled water. The method of using oral irrigator in the intervention group is taught that the person places the tip of the device at an angle almost perpendicular to the surface of the teeth and supra gingival on the teeth after brushing by trained evaluator.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental university of Mashhad

Full name of responsible person
Majid Ghayour Mobarhan

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Sponsors / Funding sources

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Sponsor

Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Sajjad Niroumand

Position

Student
Latest degree
A Level or less
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about gingival indices will be accessible after indistinguishable to patients.
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
Researchers related to academic and scientific institutions
Under which criteria data/document could be used
Only academic and scientific researchers will be allowed access to research data and can only be used for statistical analysis.
From where data/document is obtainable
Applicants can receive data if they need the e-mail address of the author responsible for public accountability.
What processes are involved for a request to access data/document
As the request, they will be answered by e-mail from the author responsible for public accountability within a month.
Comments