

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Antibacterial efficacy of non-thermal atmospheric pressure plasma against *Streptococcus mutans* and *Lactobacillus acidophilus* of carious dentin: a clinical study

Protocol summary

Study aim

evaluating of Antibacterial efficacy of non-thermal atmospheric pressure plasma against *Streptococcus mutans* and *Lactobacillus acidophilus* of carious dentin

Design

before and after the intervention dental cavity samples are entered into the transfer container of the culture medium with the help of a dental excavator. Then it is transferred to the laboratory.

Settings and conduct

The patient's sample is collected in equal amounts before and after the treatment as much as possible in Eppendorf tubes containing a reduced thioglycollate-based transfer medium without glucose. The samples are transferred to the microbiology research laboratory of Tehran University of Medical Sciences at ambient temperature within 24 hours. In the laboratory, the received samples are normalized in terms of the amount of clinical samples in them to the lowest amount of samples taken from patients. After receiving the samples, the samples will be homogenized using an ultrasonic device. Then the samples are doubled in 96-well microplates for serial dilution. Mitis Salivarius agar containing valinomycin (MS-MUTV) and De Man Rogosa Sharpe agar containing maltose (MRSM) are used as selective and differential media for the detection and counting (determination of CFU/mL) of *S. mutans* and *L. acidophilus*, respectively. After inoculation, the media are incubated for 48 hours in capnophilic conditions created by Gazpak in jars at 37°C. Then the CFU/mL of the studied bacteria will be calculated.

Participants/Inclusion and exclusion criteria

patients with cavitated dental caries, without systemic disorders and endodontic dental pain

Intervention groups

Bacteria samples will be take in patients with cavitated dental caries before and after non thermal atmospheric

pressure plasma and compared.

Main outcome variables

The amount of CFU bacteria *Streptococcus mutans* and *Lactobacillus acidophilus* before and after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056372N1**

Registration date: **2022-12-24, 1401/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-24, 1401/10/03**

Update count: **0**

Registration date

2022-12-24, 1401/10/03

Registrant information

Name

mandana karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8611 2910

Email address

mandanakarimi1374@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-10, 1401/09/19

Expected recruitment end date

2023-03-10, 1401/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Antibacterial efficacy of non-thermal atmospheric pressure plasma against *Streptococcus mutans* and *Lactobacillus acidophilus* of carious dentin: a clinical study

Public title

Antibacterial efficacy of non-thermal atmospheric pressure plasma on dental caries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

dental cavitated caries

Exclusion criteria:

systemic diseases endodontic dental pain

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **3**

number of dental caries with cavity and good access

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

dentistry school, Tehran university of medical science

Street address

no 10, 34th street, Gisha

City

Tehran

Province

Tehran

Postal code

1448985464

Approval date

2022-10-30, 1401/08/08

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.101

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

dental caries

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

The CFU of dental caries bacteria

Timepoint

before and after

Method of measurement

Mitis Salivarius agar containing valinomycin and De Man Rogosa Sharpe agar containing maltose are used as selective and differential media for the detection and counting (determination of CFU/mL) of *S. mutans* and *L. acidophilus*, respectively.

Secondary outcomes

empty

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

The studied population is people who have referred to the restorative department of Tehran Dental School for teeth restoration. After explaining the procedure to the patient and obtaining written consent from them, the patients are tested. The teeth that have cavities and clinical symptoms of spontaneous pain, irreversible pulpitis and deep decay are selected for study. The caries of the surface area (baseline samples) is removed with the help of a small size excavator, 2 mm long, 1 mm wide and 0.5 mm deep, equal to the volume of the excavator, and placed in an Ependorf tube containing a reduced transition medium based on thioglycollate without glucose. Then cold helium plasma is applied to the decay cavity by a plasma device containing helium gas (purity 99.999%) with a nozzle diameter of 3 mm, voltage of 10 kV, frequency of 6 kHz at a distance of 1 cm from the decay cavity for one minute and another sterile excavator of another sample is prepared in the vicinity and at the same level as the baseline sample,

equal to the volume of the small size exciter, and is placed in an Ependorf tube containing a reduced transfer medium based on thioglycolate without glucose. Before treatment and after treatment, as much as possible, the patient's samples are collected in equal amounts in Ependorf tubes containing a reduced thioglycollate-based transfer medium without glucose. The samples are transferred to the microbiology research laboratory of Tehran University of Medical Sciences at ambient temperature within 24 hours. Mitis Salivarius agar containing valinomycin (MS-MUTV) and De Man Rogosa Sharpe agar containing maltose (MRSM) are used as selective and differential media for tracking and counting (determination of CFU/mL) *S. mutans* and *L. acidophilus*, respectively. After inoculation, the media are incubated for 48 hours in capnophilic conditions created by Gazpak in jars at 37°C. Then the CFU/mL of the studied bacteria will be calculated. Finally, the obtained numbers will be subjected to statistical analysis. The relationship between plasma and its effect on the number of bacteria on the tested samples is investigated. The significance level in this study is considered 0.05 (P value = 0.05).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

dentistry school of Tehran university of medical science

Full name of responsible person

Mandana Karimi

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North Kargar

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1439955991

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

اکبر فتوحی

Street address

no 10, 34th or Ghaziasadollahi street, Gisha

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences

Full name of responsible person

mandana karimi

Position

post graduate 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

Tehran University of Medical Sciences

Full name of responsible person

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Raw data and analysis of bacterial counts are available for publication. Other data cannot be published.e

When the data will become available and for how long

access to data from 2024

To whom data/document is available

for researchers working in academic institutions

Under which criteria data/document could be used

For researchers, the CFU data of bacteria samples and analysis will be available.

From where data/document is obtainable

mandana karimi Mandanakarimi1374@yahoo.com

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

request to the researcher of thesis and determine clearly the purpose

Comments