

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect comparison of the diode laser 940 nm and triple antibiotic on Minocycline resistance genes (Tet M , Tet W , Tet L) in Enterococcus faecalis isolated from primary root canal infections

Protocol summary

Study aim

The effect comparison of the diode laser 940 nm and triple antibiotic on Minocycline resistance genes (Tet M , Tet W , Tet L) in Enterococcus faecalis isolated from primary root canal infections

Design

In this study, patients with 150 necrotic pulp with the inclusion criteria for entering the study are selected and sample will be taken at the endodontics department of Zahedan dental school. An unpredictable sampling will be done, so that the root canal sampling is done by a specialist in the dental clinic.

Settings and conduct

Patients with necrotic teeth are included in the study after confirmation by vitality tests. Initial sampling is performed before entering the root canal, After this stage, patients are divided into three groups: the first group received laser treatment, the second group received laser and triple therapy and the third group received the triple therapy.. After these interventions, a secondary sampling is performed, sampling procedure is carried out at the Zahedan Dental School and is performed by a endodontist. Then samples are sent to the lab for microbiological evaluations.

Participants/Inclusion and exclusion criteria

The patient have no systemic disease and have not taken antibiotics within the last 3 months. Pregnant women, patients with active periodontal disease, and patients with non-isolated or open apex are excluded from the study.

Intervention groups

Group 1; Laser intervention: With 2W power and continuously used in the root canal. Group 2; Medication and Laser intervention: First, laser is shoot, then the triple antibiotic will be dress in the root canal. Group 3; Medication intervention: Triple antibiotics enter the root canal with Lentulo

Main outcome variables

Changing the number of intracanal bacteria (e.g. Enterococcus faecalis), Investigating the presence of minocyclin resistant gene in Enterococcus faecalis, Examine the gene expression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170715035087N1**
Registration date: **2018-04-07, 1397/01/18**
Registration timing: **prospective**

Last update: **2018-04-07, 1397/01/18**

Update count: **0**

Registration date

2018-04-07, 1397/01/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3342 9482

Email address

foroughfarahi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-05-10, 1397/02/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect comparison of the diode laser 940 nm and triple antibiotic on Minocycline resistance genes (Tet M , Tet W , Tet L) in Enterococcus faecalis isolated from primary root canal infections

Public title
The effect of laser for the therapy of microbial infection in the root of teeth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patients with age ranges from 15 to 60 years who visit the Department of Endodontics at the Faculty of Dentistry in Zahedan, and are diagnosed as "necrotic pulp" with and without periapical involvement after having performed the vitality test The patients whose teeth are closed apex, with no connection between canal pulp and oral cavity The patients with no medical records in endodontic treatment, root resorption, calcification, and periodontal pocket with the depth at least 5 mm. The patients who have not been hospitalized within last three months and have not consumed antibiotics
Exclusion criteria:
The observation of necrotic pulp after entering the pulp chamber and root canal, or due to the traumatic necrosis The inability to isolate the tooth which results in the contamination of the treatment environment by saliva Pregnancy Patients who remember taking antibiotics during treatment The patient's disinterest in participating in the study

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
patients was randomly assigned to 1 of the 3 designated groups. Randomization was developed to eliminate any bias on the part of the investigators and to balance the number of patients between the treatment protocol types. Using an equal proportion randomization allocation ratio, 1 of the investigators (A.G.) created envelopes that contained concealed assignment codes that were assigned sequentially to eligible patients. It was ensured that neither the primary investigator nor the patient was aware of the treatment protocol

Blinding (investigator's opinion)

Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan university of medical sciences
Street address
Dr Hesabi Square, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816864997

Approval date
2017-10-08, 1396/07/16

Ethics committee reference number
IR.ZAUMS.REC.1396.191

Health conditions studied

1

Description of health condition studied
Infection of root canal system

ICD-10 code
B99

ICD-10 code description
Other and unspecified infectious diseases

Primary outcomes

1

Description
Number of bacteria in the root canal

Timepoint
before intervention, after intervention

Method of measurement
real time PCR

2

Description
Investigation and expression of minocyclin resistant genes in Enterococcus faecalis

Timepoint
before intervention, after intervention

Method of measurement

PCR

Secondary outcomes

empty

Intervention groups

1

Description

Laser therapy with a 2-watt diode laser (EPIC X ,BIOLASE,Irvine,CA 92618, USA) is used continuously and for each canal three times in one session.laser tip(EZTIP400&300)

Category

Treatment - Drugs

2

Description

laser and medication: First, laser diode (EPIC X ,BIOLASE,Irvine,CA 92618, USA)is shoot,The laser tip enters Only in the first session, three times,in root canal then the triple antibiotic will be dress in the root canal for a week.Triple antibiotic paste using the ratio: two tablets of metronidazole 250mg (Tehran chemie), two ciprofloxacin 250 mg tablets (Daroupakhsh-Tehran-Iran) and 5 tablets of minocycline 100 mg (Iran darou) to achieve a 1: 1: 1 ratio , Combined)

Category

Treatment - Drugs

3

Description

Control group: triple antibiotic;Triple antibiotic paste using the ratio: two tablets of metronidazole 250mg (Tehran chemie), two ciprofloxacin 250 mg tablets (Daroupakhsh-Tehran-Iran) and 5 tablets of minocycline 100 mg (Iran darou) to achieve a 1: 1: 1 ratio , Combined) The drug enters the canal with Lentulo, it remains within the root canal For a week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Dental School

Full name of responsible person

Forough Farahi

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School of Dentistry,East Azadegan Street, Zahedan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Deputy of Research of Zahedan University of Medical Sciences

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Forough Farahi

Position

Endodontics resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Eshaghali saberi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Forough Farahi

Position

Resident of Endodontics

Latest degree

Medical doctor

Other areas of specialty/work

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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

No - There is not 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

Part of the individual data and information with the outcomes including the counting of bacteria and the prevalence of faecalis in the root canal and the occurrence of antibiotic resistance genes could be shared

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Researchers working in academia and scientific institutions

Under which criteria data/document could be used

In order to replicate scientific studies and development, data can be used

From where data/document is obtainable

To the corresponding author

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

Administrative correspondence through the deputy of research and technology

Comments