

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The antimicrobial effects of curcumin essential oil gel on reducing the microbial infection at the gingival fluid of the implant-abutment interface

Protocol summary

Study aim

The antimicrobial effects of curcumin essential oil gel on reducing the microbial infection at the gingival fluid of the implant-abutment interface

Design

A clinical assessment including a single group with two samples per patient. One implant will be as a test implant and the other as a control implant (without medication).

Settings and conduct

According to the defined including and excluding criteria, 15 patients who need at least 2 implants in one jaw will be selected for the study. In the first session, curcumin essential oil gel will be inserted into the test implant fixture and no substance will be used in the control implant. The restorative abutment will be closed. Then, in the three molding sessions (10, 15, and 30 days after the restorative abutment closure session), the patients will be sampled. Then, the prepared samples will be sent to the microbiology laboratory to measure the number of bacteria (as CFU).

Participants/Inclusion and exclusion criteria

Inclusion; Patients with high levels of oral health, patients with at least 2 implants in one jaw, patients of at least 18 years of age Exclusion Patients with low levels of oral health, pregnant and lactating women, patients have received antibiotics in the last 6 months, patients with any systemic disease such as diabetes that affects oral health, patients with cigarette or alcohol addiction, patients with a history of tetracycline allergy, patients with COVID19

Intervention groups

A test implant (curcumin gel) and a control implant (without any drug)

Main outcome variables

-Independent variable: Material type (curcumin-containing gel, curcumin-free gel) Dependent variable: the amounts of Colonies Forming Units

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200919048756N1**

Registration date: **2020-09-25, 1399/07/04**

Registration timing: **prospective**

Last update: **2020-09-25, 1399/07/04**

Update count: **0**

Registration date

2020-09-25, 1399/07/04

Registrant information

Name

Solmaz Maleki Dizaj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 3161

Email address

maleki.s.89@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The antimicrobial effects of curcumin essential oil gel on reducing the microbial infection at the gingival fluid of the implant-abutment interface

Public title

The effects of curcumin gel on reducing the microbial infection at the implant-abutment interface

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with at least 2 implants in one jaw The depth of 1-3 mm for the implant's probe

Exclusion criteria:

Pregnant and lactating women Patients have received antibiotics in the last 6 months Patients with any systemic disease such as diabetes that affects oral health Patients with addiction to drugs, cigarettes or alcohol Patients with a history of tetracycline allergy

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 15

More than 1 sample in each individual

Number of samples in each individual: 2

People with two implants in one jaw. One of them will be as a test implant and the other as a control implant (without medication).

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht St, Daneshgah Ave, Tabriz University of Medical Sciences, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.TBZMED.REC.1399.605

Health conditions studied

1

Description of health condition studied

Periodontitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The measurement of the number of bacteria after placing curcumin gel in the implant for three times

Timepoint

Ten days, 15 days and 30 days after sample placement

Method of measurement

Bacterial colony counting method

Secondary outcomes

empty

Intervention groups

1

Description

Test group: one of the two implants of the patient, control group: other patient's implant, the substance used in the test group: curcumin gel with a concentration of 60 mg/ml, the substance used in the control implant: no substance, number and the duration of use: once for a month, how to use: inside the implant fixture

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Private office of Dr. Fereydoon Parnia

Full name of responsible person

Dr. Fereydoon Parnia

Street address

Fourth floor, Jahansar building, Saadi corner, Valiasr Avenue, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Solmaz Maleki Dizaj
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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

Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Fereydoon parnia

Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Not applicable.

When the data will become available and for how long

From 2021 onwards.

To whom data/document is available

There is no limitation.

Under which criteria data/document could be used

Academic members of Iranian universities

From where data/document is obtainable

Dr. Solmaz Maleki Dizaj maleki.s.89@gmail.com

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

Sending documents by email

Comments