

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the adjunctive effects of phototherapy in improving periodontal status in cancer patients during chemotherapy

Protocol summary

Study aim

The aim of this study is to investigate whether adjunctive phototherapy (along with common periodontal treatment) in patients undergoing chemotherapy leads to an improvement of the periodontal status or not

Design

A single blinded clinical trial with a control group and a parallel design R Software will be used for minimization randomization

Settings and conduct

This randomized, single-blinded trial will be conducted in a dental clinic and a specialized oncology center. All eligible patients will be assigned to intervention and control groups. Both groups will receive SRP in one session and the control group will be left until the end of a chemotherapy period. The intervention group will receive adjuvant phototherapy along with SRP. After the start of the first chemotherapy session, the patients in the intervention group will be treated with a 630 nm wavelength and energy density of 2 J/cm² laser for one day between the end of a chemotherapy period, and the involved and non-involved areas of the mouth will be treated with laser therapy. At 7 and 14 days, the main outcome parameters will be measured by a blinded investigator. Codes and numbers will be used to make outcome assessor blinded.

Participants/Inclusion and exclusion criteria

Patients <65 years undergoing chemotherapy with at least one tooth with periodontal disease will be included. Lactating and pregnant women and patients who have received interventional drugs on the periodontal condition in the last 6 months will be excluded

Intervention groups

One group of patients will receive routine periodontal treatment during a period of chemotherapy (usually within two weeks) and the other group will receive phototherapy treatment along with routine treatment.

Main outcome variables

Plaque Index; Gingival Index; Pocket Depth; Bleeding on

Probing; Pain/burning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221224056905N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Parsa Firoozi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3374 2485

Email address

parsafir2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the adjunctive effects of phototherapy in improving periodontal status in cancer patients during chemotherapy

Public title

Effects of phototherapy in improving periodontal status in cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

presence of periodontal disease at least in one tooth Age < 65 years

Exclusion criteria:

Pregnancy or lactating Medication (i.e., antibiotics) affecting periodontal status Not receiving routine periodontal treatment (SRP) in the last 6 months

Age

To **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Covariate Adaptive Randomization (Minimization) Randomization Unit: Stratified Randomization tool: R statistical software (CARAT package) Making random sequence: In this method, the first participant is randomly assigned to one of the groups, and the next participants are assigned to a group in order to balance the allocation according to the predetermined covariate variables. Allocation concealment: using numbered, sealed, and opaque envelopes

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the specific conditions of cancer patients, they will be fully informed about the type of intervention. Due to the nature of the intervention (photobiomodulation + SRP vs. SRP alone), the main researcher who is in charge of the intervention is also aware of the type of intervention. However, a separate blinded investigator is considered for accurate measurement of periodontal parameters.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA University of Medical Sciences

Street address

AJA University of Medical Sciences, School of Dentistry, Misaq Complex, East 13th Street, Ajudaniyeh, Tehran, Iran

City

Tehran

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Approval date

2022-12-17, 1401/09/26

Ethics committee reference number

IR.AJAUMS.REC.1401.153

Health conditions studied

1

Description of health condition studied

periodontal disease

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Plaque Index

Timepoint

Baseline, 7, 14 days after starting chemotherapy period

Method of measurement

The plaque index quantitatively assesses the amount of dental plaque visible on the surfaces of all teeth, except the third molars

2

Description

Gingival Index

Timepoint

Baseline, 7, 14 days after starting chemotherapy period

Method of measurement

The Gingival Index (GI) scores each site on a 0 to 3 scale, with 0 being normal and 3 being severe inflammation characterized by edema, redness, swelling, and spontaneous bleeding

3

Description

Bleeding on probing (BoP)

Timepoint

Baseline, 7, 14 days after starting chemotherapy period

Method of measurement

Visual evaluation of bleeding

4

Description

Pain/Burning

Timepoint

Baseline, 7, 14 days after starting chemotherapy period

Method of measurement

Visual Analogue Scale

5

Description

Probing Depth

Timepoint

Baseline, 7, 14 days after starting chemotherapy period

Method of measurement

The distance measured from the base of the pocket to the most apical point on the gingival margin.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In a 14-day period of chemotherapy, patients after receiving routine periodontal treatment (SRP), one day between and at the end of a period of chemotherapy with the help of a laser with a wavelength of 630 nm and an energy density of 2 J/cm² (for the purpose of photobiomodulation) involved and non-involved areas of the mouth will be irradiated. In time intervals of 0 days, 7 days, and 14 days after starting chemotherapy period, the areas inside the patient's mouth will be assessed for changes in periodontal parameters.

Category

Treatment - Other

2

Description

Control group: In a 14-day period of chemotherapy, these patients will receive only routine periodontal treatment (SRP).

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Viasr hospital, Mehraneh cancer institute

Full name of responsible person

Parsa Firoozi

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No. 629, 1st floor, Bostan 8, Ansarieh, Zanjan, Iran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Reza Fekrazad

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rezafekrazad@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Parsa Firoozi

Position

Dentist, Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

All data can be shared upon request.

When the data will become available and for how long

2024 - Q1

To whom data/document is available

For researchers only

Under which criteria data/document could be used

Not Applicable

From where data/document is obtainable

Email: Parsafir2@gmail.com

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

Obtaining permission from the publisher and journal in case of publishing the article

Comments