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
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Iran (Islamic Republic of)
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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
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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
Vliasr hospital, Mehraneh cancer institute
Full name of responsible person
Parsa Firoozi
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Sponsors / Funding sources

1

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
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