Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Evaluating the pain relieving effects of Non-Thermal CO2 Laser Therapy (NTCLT) on chemotherapy induced oral mucositis

Protocol summary

Study aim

Evaluating the pain relieving effects of single session of Non-Thermal CO2 Laser Therapy (NTCLT) in patients with chemotherapy induced oral mucositis (COM).

Design

This study is a before-after clinical trial (phase 2) on 20 patients.

Settings and conduct

Before laser irradiation, a layer of a gel with a thickness of 3–4 mm was placed on each lesion. It is a transparent gel, with high water content (87.5%) and without any anesthetic properties. The CO2 laser (λ = 10,600 nm; Lancet-2, Russia) was operated at 1W power, in continuous mode, with a de-focused hand piece, 5-6 mm distance from the surface of the gel, scanning rapidly over the lesion with a circular motion. The patients scored and recorded the contact and non-stimulate (non -contact) pain severity of their lesions. These scores were also recorded post-operatively at 4, 8, hours and then daily up to 7 days according to VAS (Visual analogue scale) scores. Any kind of adverse effects were recorded. This study was conducted at Medical Laser Research Center, ACECR, collaboration with cancer treatment centers.

Participants/Inclusion and exclusion criteria

Patient selection criteria: • Chemotherapy-induced oral mucositis with WHO grade ≥ 2 • The minimum literacy to read and write and filling the forms • More than 18 years old • Providing written informed consent after the physician's explanation about the treatment method Criteria for not selecting patients: • Pregnancy • Breastfeeding • History of Photo sensitivity or taking photo sensitizing drugs • Head and neck radiotherapy • Use of narcotic painkillers

Intervention groups

Patients with chemotherapy-induced oral mucositis with WHO grade ≥ 2

Main outcome variables

1- Non-contact pain score 2- Contact pain score

General information

Reason for update

Acronym

NTCLT

IRCT registration information

IRCT registration number: **IRCT20220220054073N1**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **retrospective**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date

2023-06-27, 1402/04/06

Registrant information

Name

Nasrin Zand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4469 0221

Email address

zand_nas@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2015-04-21, 1394/02/01

Actual recruitment end date

2019-03-06, 1397/12/15

Trial completion date

2019-05-05, 1398/02/15

Scientific title
Evaluating the pain relieving effects of Non-Thermal CO2 Laser Therapy (NTCLT) on chemotherapy induced oral mucositis

Public title
Evaluating the pain relieving effects of Non-Thermal CO2 Laser Therapy (NTCLT) on chemotherapy induced oral mucositis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Chemotherapy-induced oral mucositis with grade 1-4 according to the WHO classification index The minimum literacy to read and write and filling the forms Providing written informed consent after the physician's explanation about the treatment method
Exclusion criteria:
Pregnancy Breastfeeding History of Photo sensitivity or use of photo sensitizing drugs Head and neck radiotherapy Taking narcotic painkillers

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **1**
According to the number of painful oral lesions which can be irradiated by NTCLT
Actual sample size reached: **17**
More than 1 sample in each individual
Actual sample size in each individual: **2**
According to the number of painful oral lesions which can be irradiated by NTCLT

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Before-After Clinical Trial

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Royan Institute
Street address
No 15. Royan Alley, East Hafez St., end of North Bani Hashem St., Shahid Soleimani Highway (Resalat), Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1665659911

Approval date
2015-01-13, 1393/10/23

Ethics committee reference number
EC/93/1103

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced oral mucositis

ICD-10 code
K12.31

ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description
Non-contact (Non-stimulate) pain score

Timepoint
before laser irradiation, immediately after laser irradiation, 4 hours, 8 hours after laser irradiation and then daily until the seventh day

Method of measurement
(Visual analogue scale) VAS

2

Description
Contact pain score

Timepoint
before laser irradiation, immediately after laser irradiation, 4 hours, 8 hours after laser irradiation and then daily until the seventh day

Method of measurement
(Visual analogue scale) VAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with chemotherapy-induced oral mucositis. In this before-after clinical trial, the patients were irradiated with a single session of NTCLT. At first, the surgical staff and the patient put on protective eyeglasses. Then, the lesion and its surrounding tissue were covered with a thick layer (3-4 mm) of a non-anesthetic, completely transparent gel containing very high percentage (87.5%) of water (Abzar Darman Co., Iran). (This gel is routinely used for gastrointestinal endoscopy as a lubricating agent, sonography, etc.) Before the initiation of laser irradiation, the patient and surgical staff put on appropriate safety goggles. The CO2 laser (wavelength: 10600 nm; Lancet-2, Russia) beam (power: 1 Watt, in continuous mode) was irradiated through the gel layer. The lesion was scanned with rapid circular motion of the handpiece over the lesion, while the distance of the tip of the defocused handpiece from the surface of the gel was about 5-6 mm. The laser beam was illuminated to a circle area of the lesion (with a diameter of approximately 1cm) for 5 seconds in each pass. If the contact pain of the lesion persisted, the procedure was repeated again. The gel layer was gently wiped between the passes, and a new layer of gel was placed on the lesion.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Motamed Cancer Istitute, ACECR

Full name of responsible person
Dr. Safa Najjar Najafi

Street address
No. 45, Vahidnazari St., Aborihan St., Enqebal St

City
Tehran

Province
Tehran

Postal code
1315685981

Phone
+98 21 6640 4050

Email
safa3n@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran National Science Foundation (INSF)

Full name of responsible person
Dr. Ali Mohammad Soltani

Street address
No. 33, 5th St., North Karegar Ave

City
Tehran

Province
Tehran

Postal code
1439634665

Phone
+98 21 8800 3981

Email
info@insf.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran National Science Foundation (INSF)

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Dr. Nasrin Zand

Position
Faculty Member, Asistance Prof

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
No. 17, Nazari St., Palestine St., Enqelab St

City
Tehran

Province
Tehran

Postal code
1315795611

Phone
+98 21 6649 4649

Email
zand_nas@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person
Dr. Nasrin Zand

Position
Faculty Member, Assistant Prof

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Phone
+98 21 6649 4649

Email
zand_nas@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research

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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
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
1- Study protocol, statistical analysis map, clinical study report 2- Informed consent form

When the data will become available and for how long
1- After confirming the conclusion of the project by the sponsor 2- At the time of reviewing the final report

To whom data/document is available
1- Free access to the article 2- The sponsor

Under which criteria data/document could be used
1- To conduct research and cite the source 2- To check compliance with the principles

From where data/document is obtainable
1- Internet 2- Project administrator

What processes are involved for a request to access data/document
1- Download the article according to the rules of the journal 2- Request from the administrator

Comments