

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 ($\lambda = 10,600$ 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 Institute, ACECR

Full name of responsible person

Dr. Safa Najjar Najafi

Street address

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

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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

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1439634665

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Email

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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

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

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Latest degree

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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

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