Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Low-Level Laser therapy with two visible and Infrared wavelengths in the treatment of the symptoms of the Chemo-Therapy Induced Peripheral Neuropathy

Protocol summary

Study aim
Reduction of sensory and motor symptoms of patients
Design
Clinical trial in two groups of a parallel blind strain randomized on 40 people in two groups
Settings and conduct
Ten sessions and each session lasts for ten minutes every other day on the lower limbs in Taleghani Hospital clinic. All participants are told that they will be treated with low power laser
Participants/Inclusion and exclusion criteria
Cancer patients who took the following chemotherapy drugs during treatment: 1. Platinum compounds 2. Vinca alkaloids 3. Bortezomib 4. Taxans 5. Fluorouracil 6. Thalidomide, lenalidomide Entry into the study is subject to the absence of neuropathy due to other causes of neuropathy, including diabetes, radiculopathies, hereditary and acquired neuropathies, which can be verified at the beginning of the study through history and NCV At least 6 months have passed since the end of the patient's chemotherapy The signs and symptoms of the disease have caused a decrease in the patient's quality of life Filling out the Toronto questionnaire The patient's unwillingness to continue laser therapy
Intervention groups
An interventional clinical trial in two groups with the same population (twenty people). Laser therapy in the patients of the case group with malignant diseases and peripheral neuropathy caused by the use of chemotherapy drugs is 10 sessions and the duration of each session is 20 minutes. To perform laser therapy, a laser therapy device with the ability to apply two wavelengths, visible 630 nm and infrared 810 nm, is used. The energy density applied to the patients is 22.9 J/cm2. And in the control group, in the patients with neuropathy caused by chemotherapy, simple visible red light with an appearance similar to laser light is used, with sessions and duration similar to the group. Cases
Main outcome variables
Low power laser treatment has no complications

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240107060640N1**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**
Registration date
2024-01-08, 1402/10/18

Registrant information
Name
Gholam Reza Safavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2303 1376
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-07, 1402/10/17
Expected recruitment end date
2025-01-06, 1403/10/17
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Low-Level Laser therapy with two visible and Infrared wavelengths in the treatment of the symptoms of the Chemo-Therapy Induced Peripheral Neuropathy

Public title
effect of laser therapy on symptoms of chemotherapy induced neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cancer patients who took the following chemotherapy drugs during treatment: 1. Platinum compounds 2. Vinca alkaloids3. Bortezomib 4. Taxans 5. Fluorouracil6. Thalidomide, lenalidomide At least 6 months have passed since the end of the patient's chemotherapy. The signs and symptoms of the disease have caused a decrease in the patient's quality of life. Filling out the Toronto questionnaire
Exclusion criteria:
Entry into the study is subject to the absence of neuropathy due to other causes of neuropathy, including diabetes, radiculopathies, hereditary and acquired neuropathies, which can be verified at the beginning of the study through history and NCV.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Participating patients are blinded by the researcher
Placebo
Used
Assignment
Parallel
Other design features
This study is conducted in the form of two groups and as a clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti university of medical sciences
Street address
Taleqani Hospital Velenjak street
City
Tehran
Province
Tehran
Postal code
1653775191
Approval date
2022-08-23, 1401/06/01
Ethics committee reference number
IR.SBMU.MSP.REC.1401.662

Health conditions studied

1

Description of health condition studied
hemotherapy-induced neuropathy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Ncreasing the score obtained in the Toronto questionnaire based on history and examination and improvement of nerve conduction
Timepoint
History and examination and nerve conduction test at the beginning of the study and two weeks after the end of laser therapy
Method of measurement
Oronto neuropathy questionnaire and nerve conduction test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: n the intervention group, there are ten sessions in each session for twenty minutes, the laser is irradiated on the lower limbs on both sides below the knees and they are evaluated with a questionnaire and examination and nerve conduction test before and after the work is done.
Category

Treatment - Other

2

Description
Control group: n the control group, without the patient's knowledge, instead of the laser, ordinary visible light, which looks similar to the laser and does not have the physical characteristics of a laser, was irradiated, and like the intervention group, before and after the intervention, they were examined and filled in a questionnaire and nerve conduction test.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleqani hospital
Full name of responsible person
Gholam Reza safavi
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Taleqani Hospital Velenjak street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Deputy of research and technology
Street address
Taleqni Hospital Velenjak Street
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
hahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Gholam Reza Safavi
Position
fellowship of hematology oncology
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Full name of responsible person
Gholam Reza Safavi
Position
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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
he study protocol is available
When the data will become available and for how long
t will be available during the study
To whom data/document is available
Mr. Dr. Khosravi, Dr. Tabibi, Dr. Tabrai, and Dr. Safavi
Under which criteria data/document could be used
By publishing as an article
From where data/document is obtainable
Dr. Safavi and Taleghani Hospital
What processes are involved for a request to access data/document
By written request
Comments