

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the Efficacy of High Intensity Laser and physiotherapy in neck area on chronic non-specific pain in office workers

Protocol summary

Study aim

determination of Comparison of the Efficacy of High Intensity Laser and physiotherapy

Design

Participants will be randomly divided into intervention and control groups (laser and physiotherapy) randomly by 2 envelopes A and B randomly. RCT, single blind, is a randomized clinical trial with a parallel allocation intervention model with the main purpose of treatment.

Settings and conduct

A total review of the subjects is carried out by a physician and physical therapist, followed by subsequent visits to the participants, a questionnaire, a clinical examination and a review of paraclinical measures such as MRI. Data gathering tools included VAS, Neck Disability Index (NDI) questionnaire, Neck Pain and Disability Scale (NPDS) and Bournemouth Questionnaires. Participants evaluated by questionnaires in three stages: 1) Pre-treatment 2) Treatment dimension 3) Two weeks later treatment will be done. All participants in the study will be referred to the Khatam OL Anbiya Clinic.

Participants/Inclusion and exclusion criteria

Having neck pain, job experience, average working hours, age range

Intervention groups

Intervention group: High power laser Control group: Physiotherapy

Main outcome variables

Neck pain duration, neck pain severity, neck pain, neck pain complications, absenteeism, doctor visit, medication use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190505043483N1**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **retrospective**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Raheleh Kenareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

y.kenareh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-12, 1398/05/21

Expected recruitment end date

2019-10-13, 1398/07/21

Actual recruitment start date

2019-08-12, 1398/05/21

Actual recruitment end date

2019-11-21, 1398/08/30

Trial completion date

2019-11-21, 1398/08/30

Scientific title

Comparison of the Efficacy of High Intensity Laser and physiotherapy in neck area on chronic non-specific pain in office workers

Public title

"The effect of physiotherapy and high power laser on treatment of occupational neck pain"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having neck pain over the past 6 months Work experience greater than 1 year Having an average working time of 35 hours and more per week Age range 25 to 55 years

Exclusion criteria:

Neck and Shoulder Skin Lesions Pregnancy Systemic Disease (Neoplasm, Diabetes, Arthritis, Rheumatoid and Neuropathy) Trauma, Fractures of the spine and diseases of the cervical disc Driving Accident and Whip Lash Damage Congenital Disorders of Neck Spine

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocate to two groups. In both ultrasound laser and ultrasound physiotherapy sections, 30 samples will be selected and the control group will be selected as the control group, After entering the study, participants will be randomly divided into control and intervention groups (laser and physiotherapy) by 2 envelopes A and B based on Random Table. To hide the allocation, the type of intervention specified on the random number table will be written on paper and placed in a sealed envelope in tandem. The executor will execute

Blinding (investigator's opinion)

Single blinded

Blinding description

Before the intervention, the VAS (Visual Analogue Scale) questionnaire will be filled out first and pain intensity will be measured based on the questionnaire score (visual scale measuring pain severity is a 5 cm ruler at the left end of the word without pain and at The right end of the word is the most severe pain word written, depending on the extent of the pain in the past 2 hours, the oncologist signs. The rest of the questionnaires will also be completed. Participants will then be examined, and the researcher who completes the questionnaire will be assigned to the Blind Study Groups, and will complete the questionnaires immediately after the intervention and two weeks after the intervention. Participants will be assessed by questionnaires in three stages: 1) pre-treatment 2) post-treatment 3) two weeks after treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadughi University of Medical Sciences

Street address

Faculty of Health, Campus of Medical Sciences, Shohadaye Gomnam Boulevard, Alam Square, Yazd, Iran

City

yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۶۰

Approval date

2019-08-11, 1398/05/20

Ethics committee reference number

IR.SSU.SPH.REC.1398.058

Health conditions studied

1

Description of health condition studied

Chronic Non-Specific Neck Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of neck pain

Timepoint

Before the intervention and immediately after the intervention and 14 days after the intervention

Method of measurement

Visual Analogue Scale, neck pain index, neck pain disability scale, Neck Pain Questionnaire Bournemouth

Secondary outcomes

empty

Intervention groups

1

Description

10 sessions of laser power in 3 times, before intervention, immediately after intervention and two weeks after intervention with VELAS 158 device made in Iran

Category

Rehabilitation

2

Description

10 sessions of physiotherapy in 3 times, before intervention, immediately after intervention and two weeks after intervention with 215p device made in china

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al-Anbia Specialty and Specialty Clinic

Full name of responsible person

Dr. Amideddin Khatibi

Street address

Next to Central Laboratory, Taleghani Blvd, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Massoud Mirzaei

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International Campus Unit, Shahid Sadoughi University of Medical Sciences, 5 kilometers Old Bafgh Road, Yazd

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Raheleh Kenareh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

chemistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information exist

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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