

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Local heat Therapy on the Respiratory Indicators and Fatigue in Patients with Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

determination The Effect of Local heat Therapy on the Respiratory Indicators and Fatigue in Patients with Chronic Obstructive Pulmonary Disease

Design

A randomized trial with intervention and control groups, unblinded, random allocation by permutation block method, 48 patients with Chronic obstructive pulmonary disease

Settings and conduct

Gonabad Allame Bohlool Hospital - Patients will be randomly divided into two intervention and control groups. For control group hot pack at 37 ° C and for the intervention group, a hot pack at 50 ° C will be placed. Fatigue severity and respiratory parameters will be assessed before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Stage of 1-4 in Chronic obstructive pulmonary disease according to GOLD criteria, BMI between 18.5-25 kg/m², Alertness, ability to speak and communicate, Stable physiological status for answer questions The presence of lesions (swelling, sores, scratches, and redness) in the chest area Exclusion criteria: Structural disorder and deformity in the chest area, The history of mental disorder and hyperthyroidism based on patient reports, The presence of cardiac arrhythmia, Spirometric contraindication conditions (uncontrolled hypertension, contagious respiratory infection, active hemoptysis, recent eye or ear surgery, rupture of tympan, the recent CVA or pulmonary embolism, the history of myocardial infarction or unstable angina in recent 6 weeks)

Intervention groups

Heat therapy group at 50 ° C and control group at 37 ° C (room temperature)

Main outcome variables

Respiratory indices and fatigue severity before and after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161004030141N1**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 57254394

Email address

shahpasand.m@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Local heat Therapy on the Respiratory

Indicators and Fatigue in Patients with Chronic Obstructive Pulmonary Disease

Public title

The Effect of Local heat Therapy on the Respiratory Indicators and Fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Stage of 1-4 in Chronic obstructive pulmonary disease according to GOLD criteria BMI between 18.5-25 kg/m² Alertness, ability to speak and communicate Stable physiological status for answer questions

Exclusion criteria:

The presence of lesions (swelling, sores, scratches, and redness) in the chest area Structural disorder and deformity in the chest area The history of mental disorder and hyperthyroidism based on patient reports The presence of cardiac arrhythmia Spirometric contraindication conditions (uncontrolled hypertension, contagious respiratory infection, active hemoptysis, recent eye or ear surgery, rupture of tympan, the recent CVA or pulmonary embolism, the history of myocardial infarction or unstable angina in recent 6 weeks)

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be divided into two experimental and control groups based on permutation blocks. Six possible modes will be listed randomly and after determining the number of blocks, individuals will be allocated to the experimental and control groups, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in Gonabad University of Medical Science

Street address

Gonabad University of Medical Sciences, Next to the Asian road, Gonabad, Khorasan Razavi

City

Gonabad

Province

Razavi Khorasan

Postal code

۹۶۹۱۷۹۳۷۱۸

Approval date

2019-08-03, 1398/05/12

Ethics committee reference number

IR.GMU.REC.1398.079

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Vital Capacity

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Spirometry

2

Description

Force Vital Capacity

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Spirometry

3

Description

Forced Expiratory Volume in First Second

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Spirometry

4

Description

Peak Expiratory Flow Rate

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Spirometry

5

Description

Forced expiratory flow at 25-75% of vital capacity

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Spirometry

6

Description

FEV1/FVC

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Spirometry

7

Description

Respiratory rate

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Number per minute

8

Description

Oxygen saturation percentage (SPO2)

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Pulse Oximeter Device

9

Description

Fatigue severity

Timepoint

At baseline (before intervention), 6 days after first intervention

Method of measurement

Crop questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group will be used a hot pack for topical heat therapy, a special 25×35 standard linen bag containing hydrophilic silicate and charged by a hydrocollator up to 50 ° C. Then the hot pack will be placed in a special towel and used in anterior part of chest for 23 minutes twice a day every, heat therapy will continue for five days. Heat therapy will continue for five days.

Category

Treatment - Other

2

Description

Control group: in this group will be used a hot pack for topical heat therapy, a special 25×35 standard linen bag containing hydrophilic silicate and charged by a hydrocollator up to 37° C. Then the hot pack will be placed in a special towel and used in anterior part of chest for 23 minutes twice a day every, heat therapy will continue for five days. Heat therapy will continue for five days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonabad Allame Bohlool hospital

Full name of responsible person

Masume Shahpasand

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

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Fax

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Email

masume.shahpassand@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Research Deputy of Gonabad University of Medical Sciences

Street address

Next to the Asian Road, Gonabad University of Medical Sciences, Gonabad, Iran

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Email

Research@gmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Masume Shahpasand

Position

MSc. student in Medical-Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Ali Mohammadpour

Position

PhD In Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

Gonabad University of Medical Sciences

Full name of responsible person

Masume Shahpasand

Position

Master of Internal Surgery Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

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