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
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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
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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 Ṣhahpasand
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

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Person responsible for updating data

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Position
Master of Internal Surgery Student
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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