

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of inspiratory muscle training on the strength of respiratory muscles and the quality of life in patients with burn

Protocol summary

Study aim

Effect of inspiratory muscle training(IMT) on the strength of respiratory muscles and the quality of life in patients with burn

Design

Clinical Trial including CG with parallel groups without blindness is randomized by sequencing the software promiscuously.

Settings and conduct

This study was conducted in the Burn Ward of Imam Reza Hospital in Mashhad . The main tools used are SF36 quality of life measurement questionnaire and PBD for measuring the inspiratory muscle strength and training .The strength of the inspiratory muscles is measured by the PBD in both groups. Then in both groups routine training including CP and IS are performed for 20 minutes once a day for three weeks or more and intervention group IMT which included 30 breath twice a day for three weeks or more by PBD. It will be added to routine training in the IG , the measurement of respiratory muscle strength and completing the SF36 questionnaire will be done in both groups before and after of intervention.

Participants/Inclusion and exclusion criteria

The Inclusion Criteria : Alert , adult aged 18-60 years , TBSA:20-50% ,Burns of the back and front chest area , stable hemodynamic status , lack of burn in the lips and mouth , inhalation burns not dependent on ventilator and oxygen , Pimax less than 60 cmh2o ; The Exclusion Criteria :Sever cardiovascular and pulmonary disorders requiring medical treatment , patients who die or discharge earlier than 3 weeks.

Intervention groups

In the intervention group(IG) , in addition to chest physiotherapy (CP) and incentive spirometry(IS) , the IMT by Powerbreath Device(PBD) includ 30 breaths twice a day for three weeks or more , under supervision to researchers will be done. In the Control Group(CG) , CP and IS will be performed for 20 minutes once a day for

three weeks and more by the physiotherapist.

Main outcome variables

respiratory muscles strength and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181225042110N1**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

Registration date

2019-03-16, 1397/12/25

Registrant information

Name

elahe abazarneshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 1083

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-05, 1397/12/14

Expected recruitment end date

2019-06-04, 1398/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of inspiratory muscle training on the strength of respiratory muscles and the quality of life in patients with burn

Public title
Effect of inspiratory muscle training on the strength of respiratory muscles and the quality of life in patients with burn

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
alert Age: 18-60 years TBSA:20-50% Stable hemodynamic status Lack of burn in the lips and mouth
Absence of ventilator and oxygen inhalation burns Pimax is less than 60 cmh₂o Burns of the back and front chest area
Exclusion criteria:
Severe cardiovascular and pulmonary disorders requiring medical treatment. Patients who die or discharge earlier than 3 weeks.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Random assignment using random sequence generated by SPSS software without concealment with parallel groups is used to select patients in both intervention and control groups

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of medical sciences

Street address
Ghorayshi Building, Daneshgah Avenue

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2019-01-29, 1397/11/09

Ethics committee reference number
IR.MUMS.NURSE.REC.1397.086

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T20_T25

ICD-10 code description

Burns and corrosions of external body surface , specified by site

Primary outcomes

1

Description

Respiratory muscle strength

Timepoint

Measurement of respiratory muscle strength before the start and end of the intervention

Method of measurement

The measurement of inspiratory muscle strength by Power Breath Device

2

Description

Quality of life

Timepoint

Measurement of quality of life before the start and end of the intervention

Method of measurement

SF36 questionnaire of quality of life

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Inspiratory muscle training will be added by Powerbreath Device include 30 breath twice a day for 3 weeks and more to incentive spirometry and

chest physiotherapy In the intervention group . At first inspiratory muscle strenght will be measured in both groups (control /intervention) by Power Breath Device. The sign of inspiratory muscle weakness is inspiratory muscle strenght under 60 cmh2o. training in the intervention group is 30% of Pimax that is leveled primarily .This function will be done to investigate respiratory muscle strength and the quality of life of the patients in both groups(control/intervention) at the start and at the end of the intervention.

Category

Rehabilitation

2

Description

Control Group: The routine training including incentive spirometry and chest physiotherapy for 20 minutes once a day for 3 weeks and more will be done In the control group

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital Burn Center

Full name of responsible person

Ali Ahmadabadi

Street address

Imam Reza Hospital, The Skirts of Imam Reza Square , Ibn Sina Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

The University for Research and Technology Assistance, Mashhad University of Medical Sciences , Daneshgah Avenue

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Grant name

Grant code / Reference number

971322

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Raziye Froutan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery , Ibn Sina Avenue

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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

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Student

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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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable