Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 strenght and training .The strenght 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 strenght 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 strenght 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 abazarnezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3858 1083

Email address
abazarnezhade951@mums.ac.ir

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

emamreza@mums.ac.ir

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

vcresearch@mums.ac.ir

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

Street address

آدرس خیابان School of Nursing and Midwifery , Ibn Sina Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

froutanr@mums.ac.ir

Person responsible for scientific 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
Street address
School of Nursing and Midwifery , Ibn Sina Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
froutanr@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Elahe Abazarnezhad
Position
Student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery , Ibn Sina Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
abazarnezhade951@mums.ac.ir

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