Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

A pilot study of the evaluating of the effectiveness of balloon-blowing on dyspnea and oxygenation in non-critical adult covid-19 patients: a randomized clinical trial.

Protocol summary

Study aim

The aim of this study is to evaluate the effect of balloon-blowing on dyspnea and oxygenation in non-critical Covid-19 patients.

Design

A clinical trial with a control group, one-way blind on 80 patients. The Excel rand function was used for randomization.

Settings and conduct

Participants were selected among patients admitted to the non-intensive care unit of Booali-Sina Hospital in Qazvin, Iran, in the period from August 15, 2020, to October 31, 2020. The severity of dyspnea at rest and after 50 m walking, and O2 saturation with and without O2 therapy, were compared between the groups on the first, second, and third days. The data of two groups without labels were analyzed by SPSS Version 26 software, using unpaired T-test and analysis of variance.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ≥ 18 years old; Patients with a definitive diagnosis of Covid-19; Hospitalization in the non-intensive care unit; Dyspnea according to the patient; And O2-saturation <93% recorded by a pulse oximeter. Exclusion criteria: Pregnancy; History of lung diseases (under treatment); History of kidney diseases (under treatment); History of heart diseases; History of neurological diseases; History of allergy to latex or balloon material; Any case of prohibition from Intense aerobic activity by a physician; And the need for hospitalization in intensive care units (ICU or CCU).

Intervention groups

The patients in the control group received the medication prescribed by the relevant treatment team. The patients in the control group were asked to inflate a balloon(by blowing into it) while lying on the bed, at least 5 times a day and at least 5 times each time. The drug treatment of both groups was the same.

Main outcome variables

Changes in the severity of dyspnea at rest and after activity in the first to third days. Changes in arterial blood O2-saturation with and without oxygen therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201012049010N1**
Registration date: **2020-11-12, 1399/08/22**
Registration timing: **retrospective**

Last update: **2020-11-12, 1399/08/22**
Update count: **0**

Registration date

2020-11-12, 1399/08/22

Registrant information

Name

Mohammad Bargahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6601 6580

Email address

mamadbarg@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

2020-08-15, 1399/05/25

Actual recruitment end date

2020-10-28, 1399/08/07

Trial completion date

2020-10-30, 1399/08/09

Scientific title

A pilot study of the evaluating of the effectiveness of balloon-blowing on dyspnea and oxygenation in non-critical adult covid-19 patients: a randomized clinical trial.

Public title

The effect of balloon-blowing on dyspnea and oxygenation in non-critical adult covid-19 patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

≥ 18 years old Patients with definitive diagnosis of Covid-19 Hospitalization in non-intensive care unit dyspnea according to the patient O2-saturation <93% recorded by a pulse oximeter.

Exclusion criteria:

History of lung diseases (under treatment) History of kidney diseases (under treatment) History of heart diseases history of allergy to latex or balloon material Any case of prohibition from Intense aerobic activity by a physician the need for hospitalization in intensive care units(ICU or CCU). Pregnancy History of neurological diseases

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study were divided into two groups based on, blocks of 10, designed by Excel software in the form of random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

The collected data of the two groups were statistically analyzed without labels.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics and Research Committee of Qazvin University of Medical Sciences

Street address

Dept. of research, Qazvin University of Medical, Mavedat Ave., Shahid Beheshti Blv.,Qazvin, Iran.

City

Qazvin

Province

Qazvin

Postal code

13911/34156

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.QUMS.REC.1399.043

Health conditions studied

1

Description of health condition studied

dyspnea and hypoxia in COVID-19

ICD-10 code

U07.1+R06.

ICD-10 code description

تنگس نفس-هیپوکسی-کووید۱۹-پنومونی های وایرال

Primary outcomes

1

Description

Intensity of dyspnea at rest

Timepoint

At the beginning of the study (before the intervention) and on days 1 and 2 after the intervention.

Method of measurement

Based on Borg Modified Scale

2

Description

Intensity of dyspnea after 50 meters of walking with pulse oximeter

Timepoint

At the beginning of the study (before the intervention) and on days 1 and 2 after the intervention.

Method of measurement

Based on Borg Modified Scale

3

Description
Oxygen saturation of arterial blood without oxygen therapy
Timepoint
At the beginning of the study (before the intervention) and on days 1 and 2 after the intervention.
Method of measurement
After 5 minutes of separation from the oxygen mask by the same pulse oximeter

4

Description
Arterial blood oxygen saturation with oxygen therapy
Timepoint
At the beginning of the study (before the intervention) and on days 1 and 2 after the intervention.
Method of measurement
In the case of oxygen therapy, by the same pulse oximeter

Secondary outcomes

1

Description
Gender
Timepoint
Upon entering the study
Method of measurement
Based on identity information.

2

Description
Body mass index
Timepoint
Upon entering the study
Method of measurement
Patient weight (Kg) divided by patient height to the power of 2 (m)

3

Description
Age
Timepoint
Upon entering the study
Method of measurement
Based on identity information.

4

Description
extent of pulmonary involvement
Timepoint
Upon entering the study
Method of measurement
Based on a CT scan report

Intervention groups

1

Description
Control group: They received all the necessary medication based on the decision of the relevant medical team.
Category
N/A

2

Description
Intervention group: They received all the necessary medication based on the diagnosis of the relevant medical team (Same with the control group) ; And also the patients were asked, after receiving adequate information and training about the procedure, to inflate a balloon, by blowing up and empty it at least 5 times a day and for a minimum 5 times each time, while lying on the bed. In case of insufficient power to inflate the balloon, the balloon was substituted with a latex glove. The balloons and/or latex gloves were replaced daily.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Booali Sina Teaching Center
Full name of responsible person
Seyed Saeed Farzam
Street address
Booali Sina Street
City
Qazvin
Province
Qazvin
Postal code
34199-15315
Phone
+98 28 3333 2930
Email
boali.hospital@qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohammadali emamjomeh
Street address
Dept of research, Qazvin University of Medical Sciences, Maveddat Ave., Shahid Beheshti Blv.
City

Qazvin

Province
Qazvin

Postal code
13911/34156

Phone
+98 28 3333 7006

Email
research.dpt@qums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Mohammad Bargahi

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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No-20, Jahangir Ebrahim Ave, Jeyhoon St, tehran.

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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor

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Person responsible for updating data

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Full name of responsible person
Mohammad Bargahi

Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected data will be available after publication in the relevant journal.

When the data will become available and for how long

Immediately after the publication of the article.

To whom data/document is available

All medical researchers and institutes.

Under which criteria data/document could be used

All data will be provided to applicants by mentioning the source and the study performed.

From where data/document is obtainable

Receiving the collected data can be done by email or phone call with the original designer of the project.

What processes are involved for a request to access data/document

The data will be provided, after checking the eligibility of the applicant, immediately.

Comments