

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of using the Mask with innovative Nutrition Adaptor of Continuous Positive Airway Pressure Machine for Patients with Corona Virus Disease

Protocol summary

Study aim

To determine the effect of using the mask with an innovative nutritional adaptor on the nutritional status of the patient with COVID-19

Design

crossover RCT design was employed to achieve the aforementioned objectives. 25 patients will be assigned to join the study group. The study and control group at the same patient

Settings and conduct

25 patients infected with coronavirus disease, who were admitted in multicenter of respiratory isolation at Baghdad City. On-randomize Probability sample, two samples in same individual control measure and study trail (e.g. control=1 & study=1)

Participants/Inclusion and exclusion criteria

Inclusion: *Consent & compliance with all aspects of the study protocol, methods.*Contact male & female patients, who are 18 years old and more at the time of data collection phase*Patient diagnosis covid-19*Intensive care patient*Patient on CPAP mask*Conscious*Adult patient *Male and female.

Intervention groups

Intervention group: The starting point of the intervention phase will start by applying the mask with an innovative nutritional adaptor to respond and try to get mixed food and fluid throughout the adaptor. This step will help the patient to eat without a decrease in oxygen saturation and air leakage.

Main outcome variables

The patient gets oral feeding successfully

General information

Reason for update

Sample collection completed

Acronym

IRCT registration information

IRCT registration number: **IRCT20211022052840N1**

Registration date: **2021-11-05, 1400/08/14**

Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**

Update count: **1**

Registration date

2021-11-05, 1400/08/14

Registrant information

Name

Omar AL-Ghrai

Name of organization / entity

University of Baghdad, College of Nursing

Country

Iraq

Phone

+964 1 521 1495

Email address

omar.thamer1202a@conursing.uobaghdad.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-02-01, 1400/11/12

Actual recruitment start date

2021-11-15, 1400/08/24

Actual recruitment end date

2022-02-15, 1400/11/26

Trial completion date

2022-03-01, 1400/12/10

Scientific title

Effectiveness of using the Mask with innovative Nutrition

Adaptor of Continuous Positive Airway Pressure Machine for Patients with Corona Virus Disease

Public title

Using the Mask with innovative Nutrition Adaptor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

non-invasive ventilation patients

Exclusion criteria:

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 25

More than 1 sample in each individual

Number of samples in each individual: 2

After randomly dividing the patients of the study into two equal groups, the first group was the application of the CPAP mask (the stander hospital mask) and the second group was the application of the CPAP mask equipped with the innovative national adapter. This interference continues for 24 hours in which it monitors and records the quantities of calories and proteins that the patient took during the application of the stander hospital mask, and monitors and records the quantities of calories and protein for patients who apply the mask equipped with the innovative nutrition adapter. After the end of the first 24 hours of application, it stops and the stander hospital mask is removed from the group. The first group is replaced with the mask with the innovative nutrition adapter and the mask with the innovative nutrition adapter is stopped for the second group and replaced with the stander hospital mask and it lasts for 24 hours as well, during which the calories and proteins that were given to both groups are measured and recorded (SpO2, HR, RR, and air leakage were measured while removing the stander hospital mask to give food to the patient. Variables were also measured during feeding the patients in the two groups through the innovative nutritional adapter interface. At the end of 48 hours, the measurement was stopped and patients continued to wear the stander hospital mask, according to the center's policy

Actual sample size reached: 25

More than 1 sample in each individual

Actual sample size in each individual: 2

Each individual wears the stander hospital mask for 24 hours and then wears the mask with the innovative nutritional adapter for 24 hours

Randomization (investigator's opinion)

Randomized

Randomization description

A crossover randomized controlled trial (RCT)

Blinding (investigator's opinion)

Single blinded

Blinding description

Single-blind: the participants in the study do not know which group they have been allocated to, intervention or control

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Approval Committee, at the College of Nursing

Street address

Bab AL-Muaadham

City

Baghdad

Postal code

10001

Approval date

2021-11-02, 1400/08/11

Ethics committee reference number

3786

Health conditions studied

1

Description of health condition studied

Oral feeding with an innovation feeding adapter in a CPAP mask

ICD-10 code

J12.81

ICD-10 code description

Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description

The patient's ability to take food orally through the innovative nutritional adapter, as the daily requirement was fully provided by calculation according to the recommendations of the ESPEN guide without the influence of variables (spo2, HR, RR, and air leakage).

Timepoint

Subjects response to then apply the mask with innovation nutritional adapter will be within 24hrs

Method of measurement

Measuring the patient's ability to eat foods and liquids through the innovative adapter in a CPAP mask with

monitoring of variables

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The researcher monitors participants infected with the Coronavirus and receives the Continuous positive airway pressure (CPAP) for 24 hours to monitor whether the participants were able to remove the mask to take food and the effect of variables (pulse rate(PR), respiratory rate(RR), oxygen saturation(SPO2)and air leakage)when the mask was removed And nutritional deficiencies for participants who cannot remove the mask due to low oxygen saturation

Category

Treatment - Devices

2

Description

Intervention group: The starting point begins with placing the Continuous positive airway pressure (CPAP) mask with the innovative Nutritional adapter(feeding connection) that mask was made by the researcher on the participant instead of the mask currently placed on it. This will help the patient obtain fluids and mixed food without the need to remove the mask through the Nutritional adapter. The participant can suck the mixed fluids and food through a tube that reaches from the feeding cup or syringe feeding to the mouth. The participant will remain on the mask equipped with the innovative Nutritional adapter for 24 hours while monitoring the participant's ability to take food and liquids without the influence of variables (pulse rate(PR), respiratory rate(RR), oxygen saturation(SPO2)and air leakage) and it is measured if the patient can take the daily requirement of Nutrition and water without affecting the variables. The participants are monitored by the researcher with the help of an anesthesiologist, intensive care, and anesthesia technician

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

multicenter of respiratory isolation at Medical City Complex

Full name of responsible person

Omar AL.Ghrai

Street address

Bab AL-Muaadham

City

Baghdad

Postal code

10001

Phone

+964 1 415 0077

Email

Omar.thamer1202a@conursing.uobaghdad.edu.iq

Web page address

<https://www.medicalcity.gov.iq/ar/contact-us>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

College of Nursing, University of Baghdad

Full name of responsible person

Professor Huda Baqer Hassan, PhD. Dean

Street address

Bab AL-Muaadham campus

City

Baghdad

Postal code

10001

Phone

+964 1 521 1494

Email

Omar.thamer1202a@conursing.uobaghdad.edu.iq

Grant name

Grant code / Reference number

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

No

Title of funding source

The author of the trial is the funding source

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

College of Nursing, University of Baghdad

Full name of responsible person

Omar AL.Ghrai

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

ICU

Street address

Bab AL-Muaadham campus
City
Baghdad
Province
Baghdad
Postal code
10001
Phone
+964 1 521 1494
Email
Omar.thamer1202a@conursing.uobaghdad.edu.iq

Person responsible for scientific inquiries

Contact

Name of organization / entity
College of Nursing, University of Baghdad
Full name of responsible person
Professor Huda Baqer Hassan, PhD. Dean
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
ICU
Street address
Bab AL-Muaadham campus
City
Baghdad
Province
Baghdad
Postal code
10001
Phone
+964 1 521 1494
Email
Omar.thamer1202a@conursing.uobaghdad.edu.iq

Person responsible for updating data

Contact

Name of organization / entity
University of Baghdad, College of Nursing
Full name of responsible person
Omar AL.Ghraiir
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
ICU
Street address
Bab AL-Muaadham campus
City
Baghdad

Province
Baghdad
Postal code
10001
Phone
+964 1 521 1494
Email
Omar.thamer1202a@conursing.uobaghdad.edu.iq

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The researcher is acknowledging the scientific community to have verifiable findings of the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals.

When the data will become available and for how long

God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications

To whom data/document is available

All the related files will be shared with any scientific interested parties.

Under which criteria data/document could be used

It may be used after seeking the author's permission and acknowledging his contribution.

From where data/document is obtainable

The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail:

Omar.thamer1202a@conursing.uobaghdad.edu.iq

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

N/V

Comments

Appreciation and thanks to IRCT members for their efforts in supporting researchers