Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the Impact of a Nutrition Management Program with Inter Professional Approach on the Success of Patients Weaning Under Mechanical Ventilation in the Intensive Care Unit in selected hospitals of Isfahan University of Medical Sciences in 2020

Protocol summary

Study aim
The Impact of a Nutritional Management Program with an Inter professional Approach on Isolation Success

Design
A clinical trial with a control group, randomized, single-blind (patient), on 50 people, used the random lottery method.

Settings and conduct
At Al-Zahra Hospital, participants will be randomly divided into two experimental groups (receiving nutrition management intervention with an interprofessional approach) and a control group (receiving routine nutritional care) and the success rate of separation will be evaluated in two groups. Is blind and patients have decreased level of consciousness.

Participants/Inclusion and exclusion criteria
inclusion criteria: Obtaining informed written consent from the patient's first degree relatives - Patients under mechanical ventilation with endotracheal tube - Patients aged 18-70 years Do not have absolute and relative contraindications to intestinal nutrition (EN) - Having a level of consciousness with Glasgow scale 8 and above (T 5 and above) - Do not have diseases such as - (chronic obstructive pulmonary disease and uncontrollable active respiratory infection) - Having body mass index (BMI) less than 30 and more than 18.5 - Stay less than 72 hours in the intensive care unit -Need to continue mechanical ventilation due to brain death - Tube exit program in the first 24 hours of admission

Intervention groups
After random allocation, patients will be equally divided into experimental and control groups. The intervention of the experimental group will include nutritional management and the use of an interprofessional approach, and in the control group will receive a routine nutrition program of the intensive care unit of selected hospitals of Isfahan University of Medical Sciences.

Main outcome variables
Successful Weaning

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201229049876N1**
Registration date: **2021-01-06, 1399/10/17**
Registration timing: **prospective**

Last update: **2021-01-06, 1399/10/17**
Update count: **0**

Registration date
2021-01-06, 1399/10/17

Registrant information

Name
Hamideh Mohammadi

Name of organization / entity

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Iran (Islamic Republic of)

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hmhmn90@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-05-20, 1400/02/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Impact of a Nutrition Management Program with Inter Professional Approach on the Success of Patients Weaning Under Mechanical Ventilation in the Intensive Care Unit in selected hospitals of Isfahan University of Medical Sciences in 2020

Public title
Investigating the Impact of a Nutrition Management Program with Inter Professional Approach on the Success of Patients Weaning
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Obtaining informed written consent from the patient's first degree relatives - Patients under mechanical ventilation with endotracheal tube - Patients aged 18-70 years Do not have absolute and relative contraindications to Enteral Nutrition (EN) Have a level of consciousness of Glasgow scale 8 and above (5 T and above) No diseases such as - (chronic obstructive pulmonary disease and uncontrollable active respiratory infection) Having a body mass index (BMI) less than 30 and more than18 .5
Exclusion criteria:
Stay less than 72 hours in the intensive care unit Need to continue mechanical ventilation due to brain death The unwillingness of the patient's relatives to continue participating in the study Tube exit program in the first 24 hours of admission
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients who meet the inclusion criteria are entered into the study by easy sampling, then each sample is randomly selected by lot, so numbers 1 to 70 are placed in a box, and for each sample, The patient nurse is asked to select one of the numbers from the box. If the selected number is even, the sample is placed in the experimental group and if the selected number is odd, it is placed in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The participant does not know if he or she is in the experimental or control group, and because patients have mechanical ventilation, as the level of consciousness decreases, informed consent is obtained from the legal guardian and they are told that your patient may be in the control or experimental group .
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib St., Isfahan University of Medical Sciences and Health Services
City
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-12-09, 1399/09/19
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.609

Health conditions studied

1

Description of health condition studied
Patients under mechanical ventilation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Percentage of successful weaning
Timepoint
We will evaluate the patient's readiness for weaning with a Burn scale daily until the day of weaning or up to 15 days after the start of the study, and for patients who are ready for weaning, we will evaluate the success of weaning from the ventilator 30-120 minutes after weaning.
Method of measurement

Patient readiness for weaning with: Checklist for weaning of patients from mechanical ventilation (Burn scale) and evaluation of success and failure in weaning with the evaluation checklist for spontaneous respiration intolerance criteria in weaning from ventilator is checked

Secondary outcomes

1

Description
Weaning readiness score with the Burn tool
Timepoint
The first day of the study until the end of the study on a daily basis
Method of measurement
Patient Isolation Questionnaire from Burn Mechanical Ventilation

Intervention groups

1

Description
Intervention group: In the experimental group, a nutritional management program is implemented by an interprofessional team.This nutrition management program has a special focus on performing initial nutrition screening, complete nutritional assessment and estimating the nutritional needs of each patient, developing a diet plan based on sharing information about the nutritional status, treatment, clinical course of the disease by the patient. Interprofessional team members in joint rounds and ongoing nutrition monitoring, holding joint weekly meetings as needed to review patients' problems, case studies of patients with complex conditions, and discuss the nutrition therapy process.
Category
Treatment - Other

2

Description
Control group: In the control group, patients will receive a routine nutrition program in intensive care units in accordance with the protocol developed by the special wards of hospitals affiliated to Isfahan University of Medical Sciences, and their diet will be led by a physician. And the interprofessional nutrition group will not meet the patients in the control group and the nurse will not play a role in the patient's nutritional assessment and nutrition joint decision making, the doctor, the nutritionist will each visit the patient separately.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Maryam Eghbali
Street address
Sofe Boulevard, Shahid Keshvari Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh HaghJooe Javanmard
Street address
Hezar Jarib St., Isfahan University of Medical Sciences and Health Services, Building No. 4 - Vice Chancellor for Research and Technology
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research@mui.ac.ir
Web page address
https://research.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Eghbali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Assistant Professor

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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