

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

Country

Iran (Islamic Republic of)

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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 than 18.5

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

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget 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

Isfahan

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

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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 HaghJoee Javanmard

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Hezar Jarib St., Isfahan University of Medical Sciences and Health Services, Building No. 4 - Vice Chancellor for Research and Technology

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Web page address

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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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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