

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of applying nutritional guideline By nurses on Incidence And intensity of malnutrition in hospitalized patients in ICU

Protocol summary

Study aim

Determining the Effect of Utilization of Nutrition's Guideline by nurses on Incidence and Severity of Malnutrition in ICU

Design

Clinical practice with control group, uniformity conditions apply, with parallel groups, randomized

Settings and conduct

intensive care unit of Golestan Hospital in ahwaz as an intervention group and intensive care unit of Imam Khomeini Hospital in Ahwaz as a control group

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 14 and above 2. Hospitalization in the intensive care unit up to 24 hours after admission to the hospital 3. Stay in the intensive care unit for at least 10 days (more than 10 days), feed the patient for 10 days staying in the department and participating in the project through oral nutrition or through the stomach or tube tube Gastrostomy

Intervention groups

Evaluating the training and application of ICU patients nutrition guideline to nurses and its effect on the incidence and severity of malnutrition in hospitalized patients.

Main outcome variables

The incidence of malnutrition; Severity of malnutrition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180314039097N1**

Registration date: **2018-10-03, 1397/07/11**

Registration timing: **retrospective**

Last update: **2018-10-03, 1397/07/11**

Update count: **0**

Registration date

2018-10-03, 1397/07/11

Registrant information

Name

Mehdi Nik sefat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 5642

Email address

niksefat.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of applying nutritional guideline By nurses on Incidence And intensity of malnutrition in hospitalized patients in ICU

Public title

The Effect of using nutritional guidelines by nurses on the incidence and severity of malnutrition in patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 14 and above Admission to intensive care unit up to

24 hours after admission to the hospital Accommodation and hospitalization in the intensive care unit for at least 10 days (more than 10 days), feeding the patient during 10 days of staying in the department and participating in the project through oral nutrition or through the stomach tube or gastrostom tube

Exclusion criteria:

A patient's request to leave the study at any time, if the patient is alert hyperparathyroidism Hodgkin's disease exposure to pheochromocytoma (causes false increase in serum per-albumin levels) use of corticosteroids or non-steroidal anti-inflammatory drugs (leading to false increases in serum per-albumin levels) catching liver disease or severe infection injection of protein-containing components into the patient Severe dehydration of the patient and CVP of less than (2 cm) of water due to false increase in serum per-albumin.

Age

From **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

To prevent subversion, the person who evaluates the participants on a daily basis will not be informed about the type of treatment they receive from each participant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz University of Medical Sciences

Street address

Room 4, Ground Floor, deputy of Research and Technology Development of Ahvaz Jundishapur University of Medical Sciences, University of Ahvaz

City

ahwaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-02-17, 1396/11/28

Ethics committee reference number

IR.AJUMS.REC.1396.993

Health conditions studied

1

Description of health condition studied

Malnutrition

ICD-10 code

E43

ICD-10 code description

Unspecified severe protein-calorie malnutrition

Primary outcomes

1

Description

Incidence of malnutrition in icu patients

Timepoint

Before the intervention and ten days after the intervention

Method of measurement

Maestricht index

Secondary outcomes

1

Description

Severity of malnutrition

Timepoint

Before the intervention and ten days after the intervention

Method of measurement

Maestricht index

Intervention groups

1

Description

intervention group: the nurses will be trained in the latest version of the ICE Patient's Feeding Guideline to identify the nutritional needs of their patients and provide the food they need. This will be done under the supervision of an ICU specialist and nutritionist. This diet is then given to patients for two weeks.

Category

Treatment - Other

2

Description

Control group: For this group only routine care is provided. The diet is routine for patients.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mehdi Niksefat

Street address

Golestan Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

Ground floor, Ahvaz University of Medical Sciences
Jundishapur Health Services, University of Ahvaz,
Assistant Professor of Research and Technology

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Email

itc@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Nik sefat

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ammaniyah, Loghman Ave., Socrates Street, student
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Nik sefat

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

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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

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Statistics and the results of a general analysis of data, including the tables and charts of the study, will be published along with the conclusions of the study

When the data will become available and for how long

Start the access period 4 months after printing the results

To whom data/document is available

Data will be available to all researchers in all disciplines

Under which criteria data/document could be used

if needed, data will be provided to individuals by email.

From where data/document is obtainable

Referring to the Archives of Theses of Faculty of Nursing and Midwifery, Ahwaz University of Medical Sciences
Send an application to the email
mehdiniksefat@yahoo.com

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

in-person send mail

Comments