Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

A comparative study of the effectiveness of two methods of routine care and the implementation of the ABCDEF bundle based on the theory of appreciative leadership on pain and delirium of intensive care unit patients.

Protocol summary

Study aim
The effectiveness evaluation of routine care ABCDEF bundle implementation based on appreciative leadership theory on the hospitalization outcomes of ICU patients

Design
A clinical trial with a control group (non-randomized) with a sample size of 100 patients divided in two groups of 50 patients

Settings and conduct
In the medical Intensive Care Unit (ICU) department of Baqiatallah hospital of Tehran, after matching, the available samples are included in control and intervention groups and evaluated in terms of outcomes.

Participants/Inclusion and exclusion criteria
Non-pregnant patients with internal diseases who are 18 years old and older and who have been hospitalized for 72 hours in the ICU and do not have major cognitive and motor deficits.

Intervention groups
Patients were matched based on variables of age, gender, and the Apache 2 score, and then entered according to the study inclusion criteria, and were divided into an intervention group (recipients of ABCDEF bundle care based on appreciative leadership) and a control group (receiving routine intensive care). Then compared for outcomes of pain and delirium.

Main outcome variables
Pain; delirium; outcome of weaning from mechanical ventilation; ICU stay days

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221019056240N1**
Registration date: **2022-12-29, 1401/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-29, 1401/10/08**
Update count: **0**

Registration date
2022-12-29, 1401/10/08

Registrant information

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Rashid Jafari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-01, 1401/08/10

Expected recruitment end date
2023-01-30, 1401/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effectiveness of two methods of routine care and the implementation of the ABCDEF bundle based on the theory of appreciative leadership on

pain and delirium of intensive care unit patients.

Public title
A comparative study of the effectiveness of routine care and ABCDEF bundle implementation based on appreciative leadership theory
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Obtaining informed consent from the patient or family Hospitalization for more than 72 hours in the intensive care unit Patients with internal diseases 18 years and older patients Non-psychotic patients Non-pregnant Patients Patients who do not have severe dementia Lack of major damage to the nervous system leads to severe cognitive and motor deficits
Exclusion criteria:
Dying patients Patients having active seizures
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqitallah Medical Sciences University
Street address
Mollasadra
City
Tehran
Province
Tehran
Postal code
1435913111
Approval date
2022-10-19, 1401/07/27
Ethics committee reference number
IR.BMSU.BAQ.REC.1401.051

Health conditions studied

1

Description of health condition studied
Intensive Care
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity
Timepoint
three times a day and at 8, 16 and 24 hours and for 3 days
Method of measurement
using a visual analogue scale

2

Description
Delirium
Timepoint
three times a day and at 8, 16 and 24 hours and for 3 days
Method of measurement
Using the Persian version of the CAM-ICU tool

3

Description
Weaning from mechanical ventilation
Timepoint
Daily
Method of measurement
Record the hours of successful weaning from mechanical ventilation or reintubation (unsuccessful weaning)

Secondary outcomes

1

Description
Mortality Rate
Timepoint
At the end of the study
Method of measurement
Census of patients of both groups

2

Description
ICU length of stay
Timepoint
At the end of the study

Method of measurement
Counting the days of patients staying in the intensive care unit

Intervention groups

1

Description
Intervention group: implementation of the ABCDEF care bundle, which includes the recommendations of the American Society of Critical Care for assessment, prevention and management of pain, assessment, prevention and management of delirium and reduction of mechanical ventilation time, appropriate selection of sedative drugs, early mobilization of patients and increasing family participation and empowerment in decision-making and patient care, with appreciative leadership approach that increases the cooperation of the intensive care team. There is a need to ABCDEF bundle education in three sessions to the clinicians, nurses and physiotherapists of the intensive care unit. Then, in the implementation phase of the intervention group, the bundle elements including pain management, delirium management, spontaneous breathing trials, weaning from mechanical ventilation, selection of the appropriate sedative drugs, and early mobility according to the patient's condition with the help of the family, will be implemented with appreciative leadership approach. Finally, the outcomes of the intervention including pain, delirium and duration of mechanical ventilation, length of stay in ICU and mortality rate will be measured and compared with the control group.
Category
Treatment - Other

2

Description
Control group: Routine Intensive Care
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiatallah Hospital
Full name of responsible person
Rashid Jafari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Abbasali Imani Fooladi
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Tayyeb Moradian
Position
Associate Professor
Latest degree
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Other areas of specialty/work
Nursery
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Person responsible for updating data

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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