

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

Name

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

Ph.D.

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