Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assesment the effect of visiting based on developed protocol on physiologic parameters and delirium in patient hospitslized in ICU

Protocol summary

Study aim

Determination the effect of visiting based on Developed Protocol on Physiological Parameters and Delirium of Patients Admitted to Intensive Care Unit

Design

This study is a single- blind clinical trial. The research population is patients admitted to internal intensive care units of public hospitals of Mashhad who are over 18 years of age and have a full knowledge of Persian language, relative alertness and ability to communicate verbally or non verbally.

Settings and conduct

A clinical trial study will be carried out blindly in Imam Reza Hospital in Mashhad, so that the Delirium evaluator will not be aware of the allocation of patients to the control or intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria : The patients should be satisfied to participate in the study. They should be hospitalized in ICU. They should have the ability to communicate verbally or non-verbally. Their age should be 18-70 years. Hemodynamic stability at least 30 minutes prior to the measurment related to the study Not getting known mental illness GCS score is between 11 and 15 Exclusion criteria: Unwillingness to continue participating in the study. The lack of collaboration of the family of patients. Starting the drugs that affect on the measures of the criteria at the beginning and during the study period

Intervention groups

The intervention group are patients hospitalized in Imam Reza Hospital, Mashhad, Iran that visiting will be conducted in accordance with the protocol. The control group also includes patients similar to the intervention group that visiting will done in routine.

Main outcome variables

Physiological Indices and Arterial Oxygen Saturation and Delirium

General information

Reason for update

Sampling dates information has been corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20161229031654N2**
Registration date: **2018-01-25, 1396/11/05**
Registration timing: **prospective**

Last update: **2025-10-09, 1404/07/17**
Update count: **1**

Registration date

2018-01-25, 1396/11/05

Registrant information

Name
zahra nazari ostad
Name of organization / entity
masshad university of medical sience
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice President of Research os masshad university of medical sience

Expected recruitment start date

2018-01-26, 1396/11/06

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

2018-01-26, 1396/11/06

Actual recruitment end date

2019-02-09, 1397/11/20

Trial completion date
2019-02-09, 1397/11/20

Scientific title
Assesment the effect of visiting based on developed protocol on physiologic parameters and delirium in patient hospitslized in ICU

Public title
Effect of visiting based on designed protocol on physiologic parameters and delirium
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Satisfaction to participate in the study Ability to communicate verbally or non-verbally Age of 18-70 Hemodynamic stability at the start of the study Not getting known mental illness The patient's GCS score 11 to 15 Familiarities with Persian language
Exclusion criteria:
Unwillingness to continue participating in the study Non-cooperation of the family of patients Starting medications that affect on indices
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **84**
Actual sample size reached: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the person assessing the delirium questionnaire did not know about the allocation of patients to the control or intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ettiic Committe of Masshad Unverity of Medical Siences
Street address
Daneshgah street, Masshad Unverity Of Medical Sience, Masshad
City
Masshad
Province
Razavi Khorasan
Postal code
99191-91778
Approval date
2016-12-07, 1395/09/17
Ethics committee reference number
ir.mums.rec.1395.477

Health conditions studied

1

Description of health condition studied
Relationship of the visiting based on developed protocol on the physiological parameters and delirium of patients admitted to the intensive care unit.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Physiological parameters and delerium
Timepoint
In the beginning of the study and on the first, second and third day after the start of the study
Method of measurement
Delirium Nelon Champagon Questionnaire and monitoring devise

Secondary outcomes

empty

Intervention groups

1

Description
In the control group, the visiting will be done in the usual way in the intensive care unit.In the test group, the visiting will be done accordance with the developed protocol. The protocol includes the appointment of a visitor, the training of him on how to meet and control the correct implementation of the visit.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Zahra Nazari Ostad

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Nursing and Midwifery school, Daneshgah Street, Masshad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Zahra Nazari Ostad

Position
Master of Nursing Student

Latest degree
Bachelor

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)
Yes - There is 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
No - There is not 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
Only part of the information, such as information on the main outcome or the like, can be shared
When the data will become available and for how long
Start publishing results 6 months after the completion of the study
To whom data/document is available
Data will only be available to researchers in academia and academia
Under which criteria data/document could be used
Any analysis will be allowed
From where data/document is obtainable
To researcher email: Nazariz1@mums.ac.ir
What processes are involved for a request to access data/document
By email and within 2 weeks after receiving the request
Comments