

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 51 3276 5809

Email address

nazariz1@mums.ac.ir

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**

Ethic Committe of Masshad Unverity of Medical

Sciences

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,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fateme Hajjabadi

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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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Mashhad University of Medical Sciences

Full name of responsible person

Fateme Hajjabadi

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Instructor of Nursing

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Web page address**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