

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of care plan based on Roy adaption model on incidence and severity of delirium in patients of intensive care unit.

Protocol summary

Summary

This study aimed to evaluate the effect of care plan based on the Roy adaption model on incidence and severity of delirium in patient of intensive care unit of Besat hospital, Sanandaj, 2016. This triple blind clinical trial conducted with a sample size of 63 patients in the intervention group and 63 patients in the control group 4 months periods. At the first the intervention and control groups were selected randomly. Then the necessary training about Roy adaption model will be taught to the nurses of the intervention group. Patients in intervention group received care based on Roy adaption model. And in control group based on routines. Incidence and severity of delirium will be measured for 7 days, twice a day by Neecham questionnaires for each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052928150N1**

Registration date: **2016-06-14, 1395/03/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

Name

Hiero Hamzehpour

Name of organization / entity

Kurdistan University of Medical Sciences

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care plan based on Roy adaption model on incidence and severity of delirium in patients of intensive care unit.

Public title

Delirium and nursing care

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age over 18 years; GCS> 7; stay at least 24 hours in intensive care; lack of mental illness

Exclusion criteria: patient died during the study; and sedative hypnotic drug injection

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 63

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, Pasdaran
Boulevard, Sanandaj, Kurdistan

City

Sanandaj

Postal code

66177-13446

Approval date

2016-02-14, 1394/11/25

Ethics committee reference number

MUK.REC.1394.326

Health conditions studied

1

Description of health condition studied

delirium

ICD-10 code

F05.9

ICD-10 code description

Delirium, unspecified

Primary outcomes

1

Description

delirium

Timepoint

7 days and twice a day

Method of measurement

Neecham questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Care plan based on Roy adaption model, in the form of inter-sectorial sessions will be taught to the nurses' of intervention intensive care unit. Incompatible behaviors of physiological aspect of patients' detected and necessary care based on Roy adaption model provided.

Category

Other

2

Description

control group: In the control group patients received care based on routines of intensive care unit.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Hiero Hamzehpour

Street address

Besat Hospital, Murdoch Crossroads, Keshavarz
Street, Sanandaj, Kurdistan

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Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Jamal Seidi

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Kurdistan University of Medical Sciences, Pasdaran
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Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kurdistan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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Position

PHD in Nursing Education

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty