Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Iran (Islamic Republic of)
Phone
+98 44 3345 4870
Email address
hiero.hamzehpour@muk.ac.ir

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 Hosptal, Murdoch Crossroads, Keshavarz Street, Sanandaj, Kurdistan
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Jamal Seidi
Street address
Kurdistan University of Medical Sciences, Pasdaran Boulevard, Sanandaj, Kurdistan
City
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

Person responsible for general inquiries

Contact
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Jamal Seidi
Position
PHD in Nursing Education
Other areas of specialty/work
Street address
Kurdistan University of Medical Sciences, Pasdaran Boulevard, Sanandaj, Kurdistan
City
Sanandaj
Postal code
66177-13446
Phone
+98 87 3366 4645
Fax
Email
jamal.seidi@yahoo.comhiero.hamzehpour@muk.ac.ir
Web page address
www.muk.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Hiero Hamzehpour
Position
MS Student of Medical Surgical of Nursing
Other areas of specialty/work
Street address
Kurdistan University of Medical Sciences, Pasdaran Boulevard, Sanandaj, Kurdistan
City
Sanandaj
Postal code
Phone
+98 87 3366 4645
Fax
Email
hiero.hamzepour@muk.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Hiero Hamzehpour
Position
MS Student of Medical Surgical of Nursing
Other areas of specialty/work
Street address
Kurdistan University of Medical Sciences, Pasdaran Boulevard, Sanandaj, Kurdistan
City
Sanandaj
Postal code
66177-13446
Phone
+98 87 3366 4645
Fax
Email
hiero.hamzehpour@muk.ac.ir
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