

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of care plan based on Roy adaption model on agitation and pain in patient of intensive care unit

Protocol summary

Summary

This study aimed to evaluate the effect of care plan based on the Roy adaption model on agitation and pain 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. Agitation and pain will be measured for 7 days, twice a day by Richmond agitation scale ,and Behavioral pain scale for each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021328150N2**

Registration date: **2017-04-12, 1396/01/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

Hiero Hamzhepour

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 4870

Email address

hiero.hamzhepour@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2017-02-14, 1395/11/26

Expected recruitment end date

2017-06-16, 1396/03/26

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 agitation and pain in patient of intensive care unit

Public title

agitation and pain in patient of intensive care unit

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

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**
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

2017-02-13, 1395/11/25

Ethics committee reference number

IR.MUK.REC.1395/312

Health conditions studied

1

Description of health condition studied

agitation

ICD-10 code

R46

ICD-10 code description

Symptoms and signs involving appearance and
behaviour

2

Description of health condition studied

pain

ICD-10 code

R52

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

agitation

Timepoint

7 days and twice a day

Method of measurement

Richmond agitation scale

2

Description

pain

Timepoint

7 days and twice a day

Method of measurement

Behavioral pain scale

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

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
MUK.REC.1394.326
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
Hiero Hamzhepour
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.hamzhepour@muk.ac.irjamal.seidi@yahoo.com
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

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.com
Web page address
www.muk.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Hiero Hamzhepour
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.hamzhepour@muk.ac.ir
Web page address
www.muk.ac.ir

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