Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of implementation of a pain management algorithm on the level of consciousness and pain intensity in patients with loss of consciousness hospitalized in intensive care unit

Protocol summary

Study aim

Determining the effect of pain management algorithm on the level of consciousness and pain intensity in patients with decreased level of consciousness in hospitalized patients

Design

Patients are selected by non-random sampling method and according to entry criteria. Then, using random allocation with inertial blocks, pain management and control group will be implemented in two groups.

Settings and conduct

The method of this study is to measure the intensity of pain in patients with decreased level of consciouness between 5-8 based on the glascow scale and based on the pain management algorithm and the site of this study is the intensive care unit of Khatam Hospital in Zahedan.

Participants/Inclusion and exclusion criteria

Criteria For entering the study; 1- The patient's level of consciouness is 5 to 8 based on Glascow coma's scale 2- The patients aged 18 to 65 years old 3- Initiation of sedative infusion Non-entry criteria; 1-The patient with plegia 2- The patient with neuromuscular and sensory-motor disorders 3- The patients with chronic pain in other parts of the body, such as Migraine and back pain

Intervention groups

In the intervention group, the pain management algorithm will be implemented in three shifts per day. Pain severity scores are measured and recorded 3 times by the Behavioral Pain Scale (BPS) 3 times before the algorithm is executed (in each shift one time the algorithm is executed) and 3 times after it is completed. the control group, routine measures are undertaken to relieve, evaluate and control the pain.

Main outcome variables

level of consciousness, pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170703034873N2**
Registration date: **2018-03-14, 1396/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-14, 1396/12/23**
Update count: **0**

Registration date

2018-03-14, 1396/12/23

Registrant information

Name

fariba Yaghoubinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of implementation of a pain management algorithm on the level of consciousness and pain intensity in patients with loss of consciousness hospitalized in intensive care unit

Public title
The effect of implementation of a pain management algorithm on the level of consciousness and pain intensity in patients with loss of consciousness
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The patients aged 18 to 65 years old The patient's level of consciouness is 5 to 8 based on Glascow coma's scale Initiation of sedative infusion
Exclusion criteria:
The patient with plegia Musculoskeletal, sensory and motor disorders The patient has chronic pain in other parts of the body, such as migraine and back pain
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be convenience sampling method on the basis of entry criteria and Patients were randomly assigned to two intervention and control groups based on permutation block method.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Pardis administrative Complex of Zahedan University of Medical Sciences, Docter Hesabi Square, Zahedan
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zahedan
Province
Sistan-va-Balouchestan
Postal code
9816913396
Approval date
2018-01-28, 1396/11/08
Ethics committee reference number
IR.ZAUMS.REC.1396.357

Health conditions studied

1

Description of health condition studied
Patients with decreased level of consciousness
ICD-10 code
R29
ICD-10 code description
Other symptoms and signs involving the nervous and musculoskeletal systems

Primary outcomes

1

Description
pain intensity
Timepoint
Before The intervention and thirty minute after the intervention
Method of measurement
Behavioral Pain Scale

Secondary outcomes

1

Description
level of consciousness
Timepoint
Before and After intervention
Method of measurement
Glasgow coma Scale

Intervention groups

1

Description
" The intervention group":The pain management algorithm will be implemented in three shifts a day. Patients' pain intensity is recorded using the behavioral scale of BPS pain measurement before and after intervention. The level of consciousness is recorded using the GCS scale before and after the intervention. If pain reduces or increases, the relief measures decrease or increase.
Category
Other

2

Description
"The control group": routine measures are undertaken to relieve, evaluate and control the pain.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam-Al-Anbia hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Zahedan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available