

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 consciousness between 5-8 based on the glasgow 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 consciousness is 5 to 8 based on Glasgow 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

+98 54 3343 0059

Email address

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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 consciousness is 5 to 8 based on Glasgow 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

City

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

Fariba Yaghoubinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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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

Zahedan University of Medical Sciences

Full name of responsible person

Zahra Dehghani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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