

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of Haloperidol and Dexmedetomidine on delirium and agitation in mechanically ventilated patients following concussion admitted to the intensive care unit

Protocol summary

Study aim

Comparison of the effect of Haloperidol and Dexmedetomidine on delirium and agitation in patients under mechanical ventilation following concussion admitted to the ICU

Design

In this double-blind clinical trial study, 60 mechanically ventilated patients in the intensive care unit were randomly divided into intervention groups 1 and 2.

Settings and conduct

In this study, 60 patients under mechanical ventilation admitted to the ICU of Imam Khomeini Hospital in Ahvaz were selected by convenience sampling and randomly divided into two intervention groups 1 and 2. Patients in intervention group 1, in addition to routine care for 7 days, 2.5 mg of haloperidol in bolus and then 0.5 - 2 mg/h and patients in group 2, 1µg/kg of bolus dexmedetomidine and then 0.2-0.7 µg in Kg/h was injected by infusion. In order to blind in this study, the patient caregiver and statistical analyzer were unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Patients 18-65 years old with traumatic brain injury APACHE II criteria more than 48, RASS criteria between +1 to +4, At least 48 hours after ICU admission. Exclusion criteria include: Dissatisfaction of the patient's legal guardian, Patients who are candidates for surgery, Unstable hemodynamic status, History of mental illness or use of neuroleptics, History of drug use any contraindications to dexmedetomidine or haloperidol (allergy, arkinson's, hypotension, bradycardia), Kidney or liver dysfunction

Intervention groups

In addition to routine care, for 7 days, Patients in the first group will be injected with 2.5 mg of haloperidol as a bolus and then 2.5-5 mg/h as an infusion of haloperidol. Micrograms per kilogram per hour will be infused with

dexmedetomidine.

Main outcome variables

Delirium level, agitation rate, length of hospital stay, duration of mechanical ventilation and need for sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200803048288N1**

Registration date: **2020-09-01, 1399/06/11**

Registration timing: **retrospective**

Last update: **2020-09-01, 1399/06/11**

Update count: **0**

Registration date

2020-09-01, 1399/06/11

Registrant information

Name

Roya Darkhor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3377 7966

Email address

darkhor.r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-22, 1398/02/02

Expected recruitment end date

2020-03-02, 1398/12/12

Actual recruitment start date

2019-04-25, 1398/02/05
Actual recruitment end date

2020-03-15, 1398/12/25
Trial completion date
2020-03-18, 1398/12/28

Scientific title

Comparative study of the effect of Haloperidol and Dexmedetomidine on delirium and agitation in mechanically ventilated patients following concussion admitted to the intensive care unit

Public title

Comparative study of the effect of haloperidol and dexmedetomidine on Restlessness in mechanically ventilated patients following concussion admitted to the intensive care unit of Imam Khomeini Hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

APACHE II criteria more than 48 RASS criteria between +1 to +4 At least 48 hours after hospitalization in the intensive care unit

Exclusion criteria:

Dissatisfaction of the patient's legal guardian Patients who are candidates for surgery Unstable hemodynamic status History of mental illness or use of neuroleptics History of drug use any contraindications to Dexmedetomidine or Haloperidol (Allergy, Parkinson's, Hypotension, BradyCardiac) Renal or Hepatic Fysfunction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were selected by convenience sampling and divided into two intervention groups 1 (Haloprodil recipient) and intervention 2 (Dexmedtomidin recipient) through a random number table with even numbers assigned to intervention group 1 and odd numbers for intervention group 2. In this way, the first even number was assigned to the first patient of intervention group 1 and the first odd number to intervention group 2, and the even and selected numbers were selected and grouped from the table of random numbers of patients, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the nurse and patient caregiver did not know which group of patients the intervention group was in and whether the researcher was receiving Haloperidol or Dexmedetomidine in the ward, and the statistical analyzer was also unaware of the type of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357157941

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.AJUMS.REC.1399.155

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

Delirium

Timepoint

Every 6 hours a day for 7 days

Method of measurement

APACHE II criteria

2

Description

Agitation
Timepoint
Every 6 hours a day for 7 days
Method of measurement
APACHE II criteria

Secondary outcomes

1

Description
Duration of hospital stay
Timepoint
Daily
Method of measurement
Total days of hospitalization after receiving the intervention

Intervention groups

1

Description
Intervention group 1: In addition to routine care, patients in the first group will be injected with 2.5 mg of haloperidol as a bolus and then 2.5-5 mg / h as an infusion of haloperidol.
Category
Prevention

2

Description
Intervention group2: In addition to routine care, patients in the second group will be injected with 1 µg / kg dexmedetomidine as a bolus and then 0.2-0.7 µg / kg as an infusion of dexmedetomidine.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Roya Darkhor
Street address
Imam Khomeini Hospital, Shahid Ahvazian St., Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Vice Chancellor For Research of Ahvaz Jundishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Roya Darkhor
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available