Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Sedative and anesthetic effect of hypnotism versus acetaminophen, methadone and fentanyl in aware and awake patient in ICU ward: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the sedative and anesthetic effect of hypnotism versus acetaminophen, methadone and fentanyl in aware and awake patient in ICU ward. Design: a single blind randomized clinical trial. Setting and conduct: The eligible patients who are hospitalized in ICU ward of Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: age of 18 to 50 years; literate at least diploma; need mechanical ventilation with any reason. Exclusion criteria: consciousness disorder; acid-base disorder; psychiatric disorders. Intervention group: hypnotism for an hour three times a day for 24 hours. Control group 1: Acetaminophen 1 g intravenous every 6 hours for 24 hours. Control group 2: Methadone 2.5 mg subcutaneous every 8 hours for 24 hours. Control group 3: Infusion of fentanyl 75 mg every 6 hours for 24 hours. Primary outcome: (a) assessing agitation before intervention and 20, 40, 60 min and 1, 2, 6, 12, and 24 hours after intervention through physical examination; (b) assessing pain before intervention and 20, 40, 60 min and 1, 2, 6, 12, and 24 hours after intervention using VAS scale. Secondary outcome: assessing adverse effect (hypotension, apnea, bradycardia) 20, 40, 60 min and 1, 2, 6, 12, and 24 hours after intervention through physical examination. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as single blind

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608189014N110**

Registration date: **2016-08-26, 1395/06/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-26, 1395/06/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sedative and anesthetic effect of hypnotism versus acetaminophen, methadone and fentanyl in aware and awake patient in ICU ward: a single blind randomized clinical trial

Public title
Sedative and anesthetic effect of hypnotism versus propofol and dexmedetomidine and component of midazolam-fentanyl in aware and awake patient in ICU ward
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age of 18 to 50 years; literate at least diploma; need mechanical ventilation with any reason. Exclusion criteria: consciousness disorder; acid-base disorder; psychiatric disorders.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2016-08-06, 1395/05/16
Ethics committee reference number
IR.UMSHA.REC.1395.226

Health conditions studied

1

Description of health condition studied
Head injury
ICD-10 code
S00
ICD-10 code description
Superficial injury of head

Primary outcomes

1

Description
assessing agitation
Timepoint
before intervention and 20, 40, 60 min and 1, 2, 6, 12, and 24 hours after intervention
Method of measurement
through physical examination

2

Description
assessing pain
Timepoint
before intervention and 20, 40, 60 min and 1, 2, 6, 12, and 24 hours after intervention
Method of measurement
using VAS scale

Secondary outcomes

1

Description
assessing adverse effect (hypotension, apnea, bradycardia)
Timepoint
20, 40, 60 min and 1, 2, 6, 12, and 24 hours after intervention
Method of measurement
through physical examination

Intervention groups

1

Description
hypnotism for an hour three times a day for 24 hours
Category
Treatment - Other

2

Description
Control group 1: Acetaminophen 1 g intravenous every 6 hours for 24 hours.
Category
Treatment - Drugs

3

Description
Control group 2: Methadone 2.5 mg subcutaneous every 8 hours for 24 hours.
Category
Treatment - Drugs

4

Description
Control group 3: Infusion of fentanyl 75 mg every 6 hours for 24 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Dr Maryam Dori
Street address
Besat Hospital, Shahed Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan 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
Besat Hospital
Full name of responsible person
Dr Maryam Dori
Position
Resident of Anesthesiology
Other areas of specialty/work
Street address
Besat Hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
9188170759
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Besat Hospital
Full name of responsible person
Dr Abbas Taher
Position
Anesthesiologist
Other areas of specialty/work
Street address
Besat Hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
taher@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal

Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.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