

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