

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparing psychometric properties of “behavioral pain scale” and “Non-verbal Pain Scale” in mechanically ventilated patients admitted to the intensive care unit

Protocol summary

Summary

General objective: comparing psychometric properties of two pain assessment scales (BPS, NVPS) in non-verbal patients under mechanical ventilation. Design: Clinical trial of type methodological. Inclusion criteria include the following: patients under ventilation; with endotracheal tube for more than 24 hours, able to listen and respond with shaking the head, eyebrows or eyes; the level of agitation and sedation between +1 and -3, according to Richmond Agitation Sedation Scale (RASS). Exclusion criteria include: patients with quadriplegia; neuromuscular dysfunction and extensive injury in face and arms. Setting and conduct: This study is done on 50 to 60 patients under mechanical ventilation, hospitalized in the adults' intensive care unit of Alavi, Emam, and Fatemi hospitals of the Ardabil University of Medical Sciences. Before conducting the study, the procedure will be explained to the first degree relatives, and in case they agree to participate, the investigation will be carried out. In this study, two tools, "BPS" and "NVPS", will be used. Each tool will be filled independently by two raters and simultaneously carried out on a patient. Intervention: The behavior of each patient will be seen 15 minutes before, during, and 15 minutes after both nociceptive (turning and oral suctioning) and non-nociceptive (eye care by normal saline) procedures. Main outcome measures (variables): The patient's pain are recorded according to; two Behavioral pain scales. Then at the end of each stage the patient will be asked whether they feel pain or not. The patient's physiological symptoms are recorded by monitoring vital signs in all the six steps. After gathering enough samples, the tools will be compared and their psychometric properties will be measured

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062322881N1**

Registration date: **2015-10-28, 1394/08/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-28, 1394/08/06

Registrant information

Name

Mehdi Heidarzadeh

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 8005

Email address

m.heidarzadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences; Doctor Shahram Habibzadeh Address: University Street, Janbazan Square, Ardabil, Iran Postcode: 5618953141, Telephone (Landline): 00984533522083, Email: s.habibzadeh@arums.ac.ir

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing psychometric properties of “behavioral pain scale” and “Non-verbal Pain Scale” in mechanically ventilated patients admitted to the intensive care unit

Public title
Comparing psychometric properties of two pain assessment scales

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: patients over 18 years old; Patients in intensive care units; patients on ventilators with endotracheal tube for more than 24 hours; able to listen and respond with shaking the head; eyebrows or eyes; the level of agitation and sedation between +1 and -3; according to Richmond Agitation Sedation Scale (RASS).
Exclusion criteria: Patients with quadriplegia; those receiving muscular blocking agents or those with muscular dysfunction; Patients with Extensive injury in facial and arms; Patients with Drug addiction.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee Of Ardabil University Of Medical Science
Street address

Ardabil University Of Medical Science, University Street, Janbazan Square, Ardabil, Iran

City
Ardabil

Postal code
5618953141

Approval date
2015-05-17, 1394/02/27

Ethics committee reference number
IR.ARUMS.1394.1

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52.9

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
pain

Timepoint
15 minutes before non-nociceptive procedure, during non-nociceptive procedure, and 15 minutes after non-nociceptive procedure

Method of measurement
Two behavioural pain scales, BPS, NVPS

2

Description
pain

Timepoint
15 minutes before nociceptive procedure, during nociceptive procedure and 15 minutes after nociceptive procedure

Method of measurement
Two behavioural pain scales, BPS, NVPS

Secondary outcomes

1

Description
physiological dimensions(Vital signs)

Timepoint
15 minutes before non-nociceptive procedure, during non-nociceptive procedure, and 15 minutes after non-nociceptive procedure

Method of measurement
Monitoring vital signs

2

Description

physiological dimensions(Vital signs)

Timepoint

15 minutes before nociceptive procedure, during nociceptive procedure and 15 minutes after nociceptive procedure

Method of measurement

Monitoring vital signs

Intervention groups

1

Description

During the non-nociceptive procedure will be washed the patient's eyes with gauze soaked in normal saline for a minute at 9 am and 6 pm. And during nociceptive procedure are given turning for a minute at 9 am and 6 pm.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital

Full name of responsible person

Hoda Chokalayi

Street address

Imam Khomeini street, Ardabil, Iran

City

Ardabil

2

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Dr. Mehdi Heidarzadeh

Street address

Martyr Moadi Street, Moghaddas Ardabili Street, Ardabil, Iran

City

Ardabil

3

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Hoda Chokalayi

Street address

Ghagor jedi Ardabili Street, Ardabil, Iran

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Doctor Shahram Habibzade

Street address

University Street, Janbazan Square, Ardabil, Iran

City

Ardabil

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, Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Hoda chokalayi

Position

M.S student

Other areas of specialty/work

Street address

College of Nursing and Midwifery, Saadi Street, highway Shohada, Ardabil, Iran

City

Ardabil

Postal code

Phone

+98 45 3372 6085

Fax

Email

B.chokalaee@arums.ac.ir; yaminfaresw@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mehdi Heidarzadeh

Position

Assistant Professor

Other areas of specialty/work

Street address

College of Nursing and Midwifery, Saadi
Street, Highway Shohada, Ardabil, Iran

City

Ardabil

Postal code

Phone

+98 45 3372 6085

Fax

Email

m.heidarzadeh@arums.ac.ir; m.mahda@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mehdi Heidarzadeh

Position

Faculty member; PhD

Other areas of specialty/work

Street address

College of Nursing and Midwifery, Saadi Street,
highway Shohada, Ardabil, Iran

City

Ardabil

Postal code

Phone

+98 45 3372 8004

Fax

Email

m.heidarzadeh@arums.ac.ir ; m.mahda@gmail.com

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