

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of therapeutic touch on pain and physiological variables of patients undergoing of mechanical ventilation in intensive care units

Protocol summary

Summary

This is a randomized clinical trial with a control group in 60 patients admitted to internal and surgery ICU of Vali-e-Asr and Ayatollah Mousavi hospitals of Zanjan, Iran. The patients were divided into two groups of 30 people as the intervention and control. Before the experiment began, demographic variables and physical condition of patients were recorded. Touch therapy was conducted in four sessions. Before and after each session of touch therapy, pain and psychological variables (e.g. systolic and diastolic blood pressure, mean arterial pressure, heart rate, respiratory rate, Spo2 and heart rhythm and breathing) were recorded in both groups. Data were analyzed by chi-square test, paired and unpaired sample t test, repeated measures ANOVA by statistical software SPSS Ver.21.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061112257N3**

Registration date: **2015-09-19, 1394/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-19, 1394/06/28

Registrant information

Name

Farhad Ramezani-Badr

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 24 3527 9412

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-05-02, 1394/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of therapeutic touch on pain and physiological variables of patients undergoing of mechanical ventilation in intensive care units

Public title

The effect of therapeutic touch on pain and physiological variables of patients undergoing of mechanical ventilation in intensive care units

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who are under mechanical ventilation in intensive care units of consciousness by GCS > 8; consent of the patient's relatives or legal guardians to participate in the study; patients aged at least 15 years and a maximum of 60 years old; patients who were admitted in ICU for 24 hours; patients predicted to receive intervention for 4 times; patients who have pain on the results of the survey instrument and score more than 2 times introduced tools to gain. Exclusion criteria: patients with acute neurological

disorders or trauma to the head; patients with a history of psychological problems; transferable to other word or fatal; patients suffering from neuromuscular, quadriplegia; patients taking the drug for patients with muscle relaxants; chronic diseases (diabetes, cancer, arthritis Rheumatoid); patients during therapeutic touch their blood pressure more or less than 20% of the base rate and rate of breathing more than 25 times per minute; heart rate more than 20% of the initial state and spo2 10% decline and a lack of coordination with ventilator; patients with acute pain and patients have acute pain and short term as a result of some invasive treatment methods such as injection and venipuncture and change their positions.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vic chancellor for research (science and technology), ethical Committee, Zanjan University of Medica

Street address

Zanjan University of Medical Sciences, Azadi blvd.

City

Zanjan

Postal code

4515789589

Approval date

2014-11-14, 1393/08/23

Ethics committee reference number

ZUMS.REC.1393.154

Health conditions studied

1

Description of health condition studied

Patians with airway artificial lung

ICD-10 code

J95-99

ICD-10 code description

Other diseases of the respiratory system

Primary outcomes

1

Description

pain

Timepoint

after of every Session

Method of measurement

pain assessment of cpot scale

2

Description

systolic blood pressure

Timepoint

after of every Session

Method of measurement

mmhg , measured with a calibrated monitoring SAADAT company

3

Description

dyastolic blood pressure

Timepoint

after of every Session

Method of measurement

mmhg,measured with a calibrated monitoring SAADAT company

4

Description

mean arterial pressure

Timepoint

after of every Session

Method of measurement

mmhg,measured with a calibrated monitoring SAADAT company

5

Description

pulse rate

Timepoint

after of every Session

Method of measurement

the minutes of number,measured with a calibrated monitoring SAADAT company

6

Description

respiratory rate

Timepoint

after of every Session

Method of measurement

the minutes of number,measured with a calibrated monitoring SAADAT company

7

Description

spo2

Timepoint

after of every Session

Method of measurement

percentage minutesmeasured with a calibrated monitoring SAADAT company

8

Description

cardiac rhythm

Timepoint

after of every Session

Method of measurement

evaluation with 2 nurses

9

Description

raspiratory rhythm

Timepoint

after of every Session

Method of measurement

evaluation with 2 nurses

Secondary outcomes

1

Description

patient death

Timepoint

the patient death during the study

Method of measurement

questionnair

Intervention groups

1

Description

This study is a randomized clinical trial with two groups of control and intervention groups were divided by the blocking method available before of therapeutic touch, pain and physiologic variables is recorded in intervention group. Therapeutic touch by touch therapist is performance for patients, the time will be 20-30 minutes and after therapeutic touch, the pain and physiological variables were measured and recorded.

Category

Prevention

2

Description

In the control group, the pain and physiologic variables will be recorded and then shame touch therapy is performed for 20 -30 minutes. Then the pain and physiological variables assessed and recorded.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasri hospital, Zanjan

Full name of responsible person

Maryam Zaeimi

Street address

Valiasri educational hospital, Valiasr Road, Zanjan, Iran

City

Zanjan

2

Recruitment center

Name of recruitment center

Ayatollah Mousavi hospital, Zanjan

Full name of responsible person

Maryam Zaeimi

Street address

Mousavi educational hospital, Gavazang Road, Zanjan, Iran

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic chancellor for research, Zanjan University of Medical Sciences

Full name of responsible person

Dr. Soghrot Faghihzade

Street address

Zanjan University of Medical Sciences, Azadi 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

Vic chancellor for research, Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Maryam Zaeimi

Position
Mster of intensive care nursing

Other areas of specialty/work

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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