

# 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)

###### Phone

+98 24 3527 9412

###### Email address

ramazanibadr@zums.ac.ir

###### 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.

**City**

Zanjan

**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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Faculty of Nursing and Midwifery, Parvin Etesami St.,  
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## Person responsible for scientific inquiries

### Contact

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**Position**  
Nursing PhD, assistant professor

**Other areas of specialty/work**

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## Person responsible for updating data

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**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*