

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Effect of Music therapy on ventilation criteria of patients undergoing mechanical ventilation

#### Protocol summary

##### Summary

Introduction: The goal of this research was studying the effect of music therapy on ventilatory criteria of patients under mechanical ventilation hospitalized in special wards and using music therapy as a complementary medicine. Complications of patients under mechanical ventilation are so much and considerable. One of the factors by recovery of which the separation from ventilator take place is ventilation criteria. Nursing, using music therapy, in case of reducing stress and anxiety, can cause ventilatory criteria and wening from mechanical ventilation tool. Materials and Methods: The present research took place with two group clinical trial method in intensive care unit of Hazrat Rasoul Akram Hospital. In this research 70 patients were chosen by random sampling methodology and divided in two 35-person intervention and control groups. For intervention group relaxing music therapy was played with headphone for 30 minutes once in the morning and once in the afternoon each day. For control group headphone was used without music in two turns each for 30 minutes. In both groups ventilation criteria of respiratory rate , peak airway pressure, minute ventilation, tidal volume and the amount of spo2 were recorded.

#### General information

##### Acronym

music and ventilation

##### IRCT registration information

IRCT registration number: **IRCT201411304443N16**

Registration date: **2015-05-07, 1394/02/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-07, 1394/02/17

#### Registrant information

##### Name

Masoumeh Zakerimoghadam

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2286 2160

##### Email address

zakerimo@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2014-03-21, 1393/01/01

#### Expected recruitment end date

2014-08-23, 1393/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Music therapy on ventilation criteria of patients undergoing mechanical ventilation

#### Public title

music therapy and mechanical ventilation

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: Age above 18 and under 70 years, under respiratory support with ventilator and with modes of CPAP, PSV, SIMV, maximum number of mandatory breathing apparatus Was 10, Tracheal intubation or Tracheostomy, staying under mechanical ventilation for

more than 24 hours, the Glasgow score above 7, the acute physiology score or APACHE II less than 20, no hearing problems, Hemodynamically stable condition including heart rate under 130 beats per minutes and systolic blood pressure above 90 mm Hg. Exclusion criteria: Having COPD and ARDS, discharge; sever hemodynamic impairment, the patient's unwillingness to participate in the study, the death of patient

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Office building of Tehran University of medical Science, Keshavarz St, Tehran.

##### City

tehran

##### Postal code

#### Approval date

2014-10-18, 1393/07/26

#### Ethics committee reference number

93/130/1708/ص

## Health conditions studied

### 1

#### Description of health condition studied

patients undergoing mechanical ventilation

#### ICD-10 code

J95.0 , J9

#### ICD-10 code description

Chronic respiratory failure, Acute respiratory failure

## Primary outcomes

### 1

#### Description

peak airway presser

#### Timepoint

30 minutes in morning and 30 minutes in evening

#### Method of measurement

Seen from the ventilator monitor and recorded in H2O cm

### 2

#### Description

tidal volume

#### Timepoint

30 minutes in morning and 30 minutes in evening

#### Method of measurement

Seen from the ventilator monitor and recorded in ml

### 3

#### Description

respiratory rate

#### Timepoint

30 minutes in morning and 30 minutes in evening

#### Method of measurement

Seen from the ventilator monitor and recorded in terms of the number per minute

### 4

#### Description

minute ventilation

#### Timepoint

30 minutes in morning and 30 minutes in evening

#### Method of measurement

Seen from the ventilator monitor and recorded in ml

### 5

#### Description

spo2

#### Timepoint

30 minutes in morning and 30 minutes in evening

#### Method of measurement

From pulse oximeter monitor in percentile

## Secondary outcomes

### 1

#### Description

respiratori rate- spo2-peak airway presser-tv-mv

#### Timepoint

Time zero and ten and twenty and thirty minutes after the start of Music Therapy

#### Method of measurement

by using ventilator monitorig

## Intervention groups

### 1

#### Description

In control group, the headphone was also used to prevent the annoying noises and patients were evaluated twice for one day that the duration of each one was 30 minutes between 9:30-10 AM and 16-16:30 PM. Restrictions imposed were same as intervention group. As the intervention group, all reparatory parameters and other variables were also measured in control group.

#### Category

Other

### 2

#### Description

In intervention group, instrumental music was played by headphone twice for one day that the duration of each one was 30 minutes between 9:30-10 AM and 16-16:30 PM. The music used in the study was track 1 of Arnd Stein's masterwork, namely Peace in Dream. This track is about 30 minutes. We chose the evening and morning to intervention, because of minimal medical interventions in these times. The researcher was present during the intervention. The respiratory parameters were recorded from the monitor at specified times. And during the study in intervention group, other nonemergency nursing interventions were stopped. The time for recording the respiratory parameters was defined as follows: before using the headphone and playing the music as 0, 10 minutes after playing music as 10, 20 minutes after playing music as 20, 30 minutes after playing music as 30; and all parameters were recorded from monitor of ventilator.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

rasol akram hospital

##### Full name of responsible person

masoomeh zakeri moghadam

##### Street address

Hazrat Rasoul Akram hospital, Niyayesh St, Sattarkhan St, Tehran.

##### City

tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

masume zakeri moghadam

#### Street address

tohid square

#### City

tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

masoome zakeri moghadam

##### Position

board of scientific

##### Other areas of specialty/work

##### Street address

Tehran University Of medical Science, School of Nursing and Midwifery, Nosrat St, Tohid Sq, Tehran.

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## Person responsible for scientific inquiries

#### Contact

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##### Other areas of specialty/work

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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*