

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The Effect of rhythmic breathing on the anxiety and pain of dressing in burned

Protocol summary

Summary

(1)The purpose of this Experimental clinical trail with the control group is to investigate the effect of rhythmic breathing on pain and anxiety of burn dressing change in hospitalized patients admitted to Ayatollah Mousavi Educational Hospital Zanjan Province. (2) Sample: Available sample of 60 patients,(3) Anxiety and Pain will be assessed before going to dressing room and after dressing in experimental group and control group. This work will continue for three consecutive day (4) Aged 18 to 60, TBSA %9-35, burn degree 2 or 2 and 3, able to speak and understand Persian, wound dressing by wards' routines, no self-inflicted burn. For prevent bias, initially, the control group and then the intervention group entered the study.(5) The procedure will be explained to each patient. A written instruction about the procedure will be given to the experimental group. (6) Pain and anxiety will be measured with Visual Analogue Scale (VAS) scoring procedure: The scores of each tool range from 0-10.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052928153N1**

Registration date: **2016-07-02, 1395/04/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name

Hamed Azizkhani

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-05, 1395/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of rhythmic breathing on the anxiety and pain of dressing in burned

Public title

The Effect of rhythmic breathing on the anxiety and pain of dressing in burned

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:The patient is in hospital four days:
Older than 18:Do not have a burn-relief: Lack of electricity and chemical burns and burning: The level of between 10% to 45% with some degree burns include 1, 2, 3:The ability to communicate verbally and understand the language of Persian: Ability to read and write: The ability to carry out co-respiratory: Lack of drug addiction: Lack of mental illness: severe hearing and vision

problems have. The exclusion criteria: reluctance of patients to participate in research : Patients who for any reason can not reach the necessary skills: Discharged during the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Between The Highway Martyr Chamran and Martyr Sheikh Fazlullah Nuri, Martyr Hemmat Highway ,Tehran, Iran.

City

Tehran

Postal code

4798-19395

Approval date

2016-05-07, 1395/02/18

Ethics committee reference number

IR.IUMS.REC 1395.9211196251

Health conditions studied

1

Description of health condition studied

Burns and corrosions

ICD-10 code

T29, T31

ICD-10 code description

Burns and corrosions of multiple body regions, Burns

classified according to extent of body surface involved

Primary outcomes

1

Description

The pain during burn dressing

Timepoint

Before and after dressing in the intervention group and control during three consecutive days

Method of measurement

Visual Analogue Scale (VAS)

2

Description

The anxiety during burn dressing

Timepoint

Before and after dressing in the intervention group and control during three consecutive days

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

NO

Timepoint

NO

Method of measurement

NO

Intervention groups

1

Description

Intervention group: This group will receive rhythmic breathing. subjects will be asked to sit in a comfortable semi -fowlers position in their beds and perform the following procedure for 20 minutes: (a) close your eyes (b) relax their muscles (c)breath slowly with a three-rhythm pattern of inhale, exhale, and rest, so that air from the nose and then slowly breathe out through your mouth (d) In all the time of breathing to increase the size of the chest, to move abdomen and his shoulders note Subjects' ability to use the technique will be verified by observing.

Category

Other

2

Description

Control group: No intervention will be performed

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Educational Hospital Zanjan Province

Full name of responsible person

Hamed Azizkhani

Street address

Ayatollah Mousavi Educational Hospital, Gavazng, Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Assistance of Iran University of Medical Sciences

Full name of responsible person

Syed Ali Javad Mousavi

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Iran University of Medical Sciences, Between The Highway Martyr Chamran and Martyr Sheikh Fazlullah Nuri, Martyr Hemmat Highway ,Tehran, Iran.

City

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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

Research Assistance of Iran 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**

Iran School of Nursing and Midwifery, Iran University of Medical Science

Full name of responsible person

Mehri Bozorgnejad

Position

MSc

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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