Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of jaw relaxation on pain of burn dressing change in hospitalized patients of Shahid Motahari Clinical Educational Center in 2009.

Protocol summary

Summary

The purpose of this randomized clinical trial is to investigate the effect of jaw relaxation on pain intensity and anxiety of burn dressing change in hospitalized patients admitted to Shahid Motahari Burn Center in Tehran. Sample: convenience sample of 120 patients, 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. Sampling procedure: randomly assigned using minimization to either experimental or control groups. Pain intensity and anxiety will be measured with Visual Analogue Scale (VAS) and Burn Specific Pain Anxiety Scale (BSPAS) respectively. Scoring procedure: The scores of each tool range from 0-100. The procedure will be explained to each patient. A written instruction about the procedure will be given to the experimental group. They will practice the technique for 20 minutes before going to dressing room. Pain anxiety will be assessed before and after intervention (before going to dressing room) and after dressing in experimental group. In control group it will be assessed before and after dressing. Pain intensity will be also assessed after dressing in both groups. Finally four structured questions will be asked from experimental group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803202019N1**
Registration date: **2009-07-25, 1388/05/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-07-25, 1388/05/03

Registrant information

Name
Fahimeh Mohammadi Fakhar
Name of organization / entity
Faculty of Nursing & Midwifery, Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 26 1224 2296
Email address
frafii@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-01-21, 1388/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of jaw relaxation on pain of burn dressing change in hospitalized patients of Shahid Motahari Clinical Educational Center in 2009.

Public title

The effect of jaw relaxation on pain of burn dressing change in hospitalized patients of Shahid Motahari Clinical Educational Center in 2009.

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Patients in acute phase of burn injury, thermal burn, absence of face and neck burn, presence of psychological disorders currently or previously, presence of complications related to neurological disorders leading to numbness in burned tissues, presence of severe visual and/or hearing problems
Exclusion criteria: Inability to do any stages of the procedure for any reason, inability to achieve mastery in jaw relaxation technique for any reason, surgical procedures for skin graft during the study interventions, application of biological dressings to the skin
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Nursing and Midwifery, Iran University of Medical Sciences
Street address
Rashid Yasemi St., Vali-Asr Ave., Po-Box: 19395-4798, Tehran, Iran.
City
Tehran
Postal code
19964
Approval date
2009-05-01, 1388/02/11
Ethics committee reference number
1255518

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
Intensity of burn dressing pain
Timepoint
After dressing
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Pain anxiety with burn dressing
Timepoint
Before and after intervention (before dressing) and after dressing in experimental group and also before and after dressing in control group
Method of measurement
Burn Specific Pain Anxiety Scale (BSPAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will receive Jaw relaxation. subjects will be asked to sit in a comfortable semi -fowlers position in their beds and perform the following procedure for 20 minutes: (a) let the lower jaw drop slightly (b) keep the tongue quiet and resting in the bottom of the mouth (c) let the lips get soft (d) breath slowly with a three-rhythm pattern of inhale, exhale, and rest (e) stop forming words and do not even think words. Subjects' ability to use the technique will be verified by observing for four criteria: (a) face relaxed (b) no grimace or frown (c) not talking (d) slow respirations (2 points each). Mastery is defined as a score of 7 out of 8 points.
Category
Behavior

2

Description

Control group: No intervention will be performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinical Educational Center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. F. Oskouie

Street address

Center for Nursing Care Research 2nd building of School of Nursing and Midwifery, Rashid Yasemi St., Vali-Asr Ave., Po-Box: 19395-4798, Tehran, Iran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Faculty of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Fahimeh Mohammadi Fakhar

Position

Masters Degree in Nursing (MSN)

Other areas of specialty/work

Street address

NO 66, 12 Metri-e Enghelab St., Talaghani Ave., Karaj, Tehran, Iran.

City

Karaj

Postal code

31348-13354

Phone

Fax

Email

mohamadifahimeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Center for Nursing Care Research, Iran University of Medical Sciences

Full name of responsible person

Dr Forough Rafii

Position

PHD

Other areas of specialty/work

Street address

Center for Nursing Care Research 2nd building of School of Nursing and Midwifery, Rashid Yasemi St., Vali-Asr Ave., Po-Box: 19395-4798, Tehran, Iran.

City

Tehran

Postal code

19964

Phone

+98 21 8247 1155

Fax

+98 21 8879 3805

Email

frafii@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Fahimeh Mohammadi Fakhar

Position

Masters Degree in Nursing (MSN)

Other areas of specialty/work

Street address

NO 66, 12 Metri-e Enghelab St., Talaghani Ave., Karaj, Tehran, Iran.

City

Karaj

Postal code

31348-13354

Phone

Fax

Email

mohamadifahimeh@yahoo.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