

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparing the effect of muscle relaxation and mental imagery on severity and anxiety of pain in patients with second degree burn wounds.

Protocol summary

Summary

The aim of this study was to compare the efficacy of muscle relaxation and mental imagery on severity and anxiety of pain in patients with second degree burn wounds. This study is a quasi-experimental study of a clinical trial which was conducted on 135 patients admitted to Motahari hospital who were selected by convenience method. In one-month period (September 2015), 45 patients who were hospitalized in the male ward 1 & 2 and had the criteria, were placed in the control group and severity and anxiety of their pain during acute phase of their burn (first 48 hours after burn), before and after dressing change along with routine intervention (receiving morphine based on the weight before dressing), were measured. After the discharge of control group patients and admitting new patients in the male ward 1 and 2, 45 male patients in ward 1, and 45 male patients in ward 2 were given muscle relaxation technique and mental imagery technique education respectively and the severity and anxiety of their pain during acute phase of their burns (first 48 hours after burn), before and after dressing along with routine interventions (receiving morphine based on the weight before dressing), were measured. Sampling the intervention groups in male wards lasted for two months (October-November 2015). Then the severity and anxiety of the pain before and after dressing and amount of morphine consumption in the first and second days of the burn in all three groups were compared and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512194443N20**

Registration date: **2016-02-01, 1394/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-01, 1394/11/12

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 Science

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of muscle relaxation and mental imagery on severity and anxiety of pain in patients with second degree burn wounds.

Public title

Comparing the effect of muscle relaxation and mental imagery on severity and anxiety of pain in patients with second degree burn wounds.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients should be male; patients have 2nd degree burn wounds; patients have full consciousness and be able to cooperate; patients have 20 to 45 years of age; patients have unintentional and non-inhalation burns; patients have 60-40% of their body surface area burned; patients be in the acute phase of burn (first 48 hours after burn); patients have no underlying disease (neurological disorders and numbness in the extremities, mental disorders such as; Alzheimer or memory disorders, muscle diseases, electrolyte disorders including; hyponatremia and hypocalcemia) ; patients have no known morbid anxiety problems. Exclusion criteria: Not cooperating until the end of the intervention; treatment duration more than a month in the control group patients; the use of neuromuscular blocking agents(baclofen, dantrolene, etc.); excessive use of morphine and tranquillizers before entering the dressing room(morphine is injected by patient weight and at intervals of 4-6hours, otherwise, the patient will be removed from the sample), the need for EE&G surgery (Early Excision Graft), scartomy or fasciotomy in the severe burns phase.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Not 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 of Tehran University of Medical Sciences

Street address

The sixth floor of the Central Building, St, Quds St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2015-10-27, 1394/08/05

Ethics committee reference number

IR.TUMS.REC.1394.1040

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T30.6

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Pain severity

Timepoint

Before and after dressing in the first and second days of the burn (acute phase of burn)

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Pain anxiety

Timepoint

Before and after dressing in the first and second days of the burn (acute phase of burn)

Method of measurement

Burn Specific Pain Anxiety Scale (BSPAS)

Intervention groups

1

Description

Control group: control group patients receive routine interventions (receiving morphine based on the weight before dressing) and do not interfere in this group.

Category

Treatment - Other

2

Description

Intervention group 1: patients in ward 1 were taught muscle relaxation technique along with routine interventions (receiving morphine based on the weight before dressing).

Category

Treatment - Other

3**Description**

Intervention group 2: patients in ward 2 were taught mental imagery techniques along with routine interventions (receiving morphine based on the weight before dressing).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Motahari Hospital

Full name of responsible person

Fatemeh Delfani

Street address

Rasheed Yasemi St, Above Vanak Square, Valiasr St.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Street address

Faculty of Nursing and Midwifery, Eastern Nosrat St, Tohid Square, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, 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**

Nursing- Midwifery Faculty of Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Position

Ph.D/Scientific Panel Member

Other areas of specialty/work**Street address**

Faculty of Nursing and Midwifery, Eastern Nosrat, Tohid Square, Tehran

City

Tehran

Postal code**Phone**

+98 21 6692 7171

Fax**Email**

Zakerimo@sina.tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing- Midwifery Faculty of Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Position

Ph.D/Scientific Panel Member

Other areas of specialty/work**Street address**

Faculty of Nursing and Midwifery, Eastern Nosrat St, Tohid Square, Tehran

City

Tehran

Postal code**Phone**

+98 21 6692 7171

Fax**Email**

Zakerimo@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Nursing- Midwifery Faculty of Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Position

Ph.D/Scientific Panel Member

Other areas of specialty/work**Street address**

Faculty of Nursing and Midwifery, Eastern Nosrat St,

Tohid Square, Tehran

City

Tehran

Postal code

Phone

+98 21 6692 7171

Fax

Email

Zakerimo@sina.tums.ac.ir

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