

# 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**

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**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*