# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of mandala staining on pain and anxiety from burning dressing pain

## Protocol summary

**Study aim**
The effect of mandala staining on pain and anxiety from burning dressing pain

**Design**
Randomized control-trial (RCT), community-based and pragmatic, with parallel groups, non-blinded

**Settings and conduct**
This is a randomized control-trial on 60 patients with second-degree burning hospitalized in Arak city Valie-assr hospital. Categorization will be done, using randomized blocks, and into intervention and control groups with equal number of participants.Firstly, anxiety scores and pain intensity will be assessed using burn specific pain anxiety scale (BSPAS) standard query and immediately Mandala color palette with 12 color pen will be allocated to the patients. Each patient has a 30 minutes time to coloring the shape followed by 5 minutes resting time and the anxiety is measured. Fifteen minutes post-dressing, the BSPAS and pain intensity are measured. In control group, at the initial step of the study and 15 minutes post-dressing, BSPAS and pain intensity are measured.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria : 1- Patients with superficial second-degree burn 2- Hospitalization in burning wards 3-Age range of18-60 years 4- To be under wound-dressing, at least for one session 5- Daily dressing 6- Staining ability 7- Not to use psychotropic drugs and not to be a psychological disorder 8- No addiction Non-inclusion: 1- Patients with a history of previous burning 2- Needs to surgery (Graft or debridement) for burning wound 3- Burning wound infection

**Intervention groups**
1- staining group 2-control group

**Main outcome variables**
pain and anxiety

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190122042452N1**
Registration date: **2019-08-11, 1398/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-11, 1398/05/20**
Update count: **0**

**Registration date**
2019-08-11, 1398/05/20

**Registrant information**

**Name**
Hamidreza Sadeghi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-05-02, 1398/02/12

**Expected recruitment end date**
2019-09-11, 1398/06/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

The effect of mandala staining on pain and anxiety from burning dressing pain

**Public title**
The effect of mandala staining on pain and anxiety burning dressing
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with superficial second-degree burn Hospitalization in burning wards Age range of 18-60 years To be under wound-dressing, at least for one session Daily dressing Staining ability Not to use psychotropic drugs and not to be a psychological disorder No addiction
**Exclusion criteria:**
Patients with a history of previous burning Needs to surgery (Graft or debridement) for burning wound Burning wound infection
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, patients with second degree burn are randomly devided to block methods. By assigning the letter A to the intervention group (Mandala staining) and the letter B to the control group.The six modes of BAAB, ABBA, BABA, BBAA, AABB and ABAB were Written in separate sheets and dropped in to the dish and the composition was written on it and again that sheet was thrown in to the dish.This procedure was repeated 15 time and each time the composition was written on each sheet in order to the order written in the previous sheet was memorized. Then to each of the letters, anumber from one to sixty consecutiv letters were assigned in sequence. And each letter was placed inside an envelop and written on the envelope of that letter. Each time the patient is selected, one of the envelops is opened and the patient is to be placed in the intervention or control group.Respectiuoly. patient were then assigned to intervention and control grops.
**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**
Etihics committee of Arak University Of Medical Sciences
**Street address**
Associate professor Of Research and Technolo gy, Univercit Of the Great Prophet, Basij square, Sardasht Region Arak
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Approval date**
2012-02-24, 1390/12/05
**Ethics committee reference number**
IR.ARAKMU.REC.1397.348

## Health conditions studied

### 1

**Description of health condition studied**
Anxiety by burning
**ICD-10 code**
**ICD-10 code description**

### 2

**Description of health condition studied**
Pain of burning
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Pain anxiety
**Timepoint**
Before intervention, 35 minutes after intervention and 15 minutes after dressing
**Method of measurement**
Burn Specifice Pain Anxiety Scale

### 2

**Description**
Intensity of pain
**Timepoint**
Before the intervention and 15 minutes after the dressing

**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: In the intervention group, after painting the color of the mandala pattern for 30 minutes before changing the dressing, they stained the mandala pattern
**Category**
Behavior

### 2

**Description**
Control group: In the control group, routine actions are only performed
**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Valiasr Hospital
**Full name of responsible person**
Hamid Reza Sadeghi
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Valiasr Hospital, Valiasr Square, Arak
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Mohammad Arjmand Zadegan
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Associate Professor of Research and Technology, University of the Great Prophet, Basij Square, Sardasht Region
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arjomandzadegan@arakmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Arak University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Hamid Reza Sadeghi
**Position**
Head of Nursing Services
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
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## Person responsible for scientific inquiries

**Contact**
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Kobra Rahzani

**Position**
Associate Professor

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## Person responsible for updating data

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**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available