

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 of 18-60 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)

Phone

+98 86 3417 3463

Email address

ha.sadeghi@arakmu.ac.ir

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 divided 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 times 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, a number from one to sixty consecutive letters were assigned in sequence. And each letter was placed inside an envelope and written on the envelope of that letter. Each time the patient is selected, one of the envelopes is opened and the patient is to be placed in the intervention or control group. Respectively, patients were then assigned to intervention and control groups.

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 Arak University Of Medical Sciences

Street address

Associate professor Of Research and Technology, University 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 Specific 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

Street address

Valiasr Hospital, Valiasr Square, Arak

City

Arak

Province

Markazi

Postal code

38816-88845

Phone

+98 86 3222 2003

Email

ha.sadeghi@arakmu.ac.ir

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

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjmand Zadegan

Street address

Associate Professor of Research and Technology,
University of the Great Prophet, Basij Square,
Sardasht Region

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3645

Email

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

Street address

The Third floor, the Blue wings, the university
complex of the Great Prophet, Basij Square, Sardasht
area

City

Arak

Province

Markazi

Postal code

6941-7-38481

Phone

+98 86 3417 3502

Email

ha.sadeghi@arakmu.ac.ir

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

Arak University of Medical Sciences

Full name of responsible person

Kobra Rahzani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Third floor, Blue wings, university complex of the
Great Prophet, Basij Square, Sardasht area

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3463

Email

K.rahzani@yahoo.com

Street address

Third floor, Blue wings, university complex of the
Great Prophet, Basij Square, Sardasht area

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3502

Email

ha.sadeghi@arakmu.ac.ir

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

Person responsible for updating data

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