Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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)

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 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
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

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

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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