Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mandala coloring on anxiety and pain in patients undergoing bone marrow biopsy

Protocol summary

Study aim
This study will be conducted with the aim of investigating the effect of mandala coloring on anxiety and pain in patients who are candidates for bone marrow sampling.

Design
A clinical trial that includes intervention and control groups and based on block selection, which is conducted on 80 patients randomly.

Settings and conduct
All patients who are candidates for bone marrow sampling in Arak city in Khansari Hospital, which is performed before sampling, the level of pain and anxiety is measured from the Spielberger questionnaire and using a numerical pain rating scale. A code will be given to the control and intervention groups to prevent the statistical analyst from knowing the type of groups and to prevent bias in the data analysis by the statistical analyst.

Participants/Inclusion and exclusion criteria
Entry requirements: Willingness to participate in research. Be in the age range of 18 to 45 years. To undergo bone marrow sampling for the first time. According to the Spielberger anxiety questionnaire, the research unit has mild or moderate anxiety. To treat pain and anxiety, they have not taken medicine or are not undergoing therapeutic intervention. Bone marrow sampling of the research units should be performed by a single physician. Sampling is done from the iliac region. Exit conditions: Failure to complete the procedure or repeating the procedure on the patient for any reason Unwillingness to continue participating in the intervention Taking painkillers and anti-anxiety drugs with the doctor's opinion during the procedure Failure to answer all questionnaire questions

Intervention groups
All candidate patients for bone marrow sampling in Arak city The intervention performed in the intervention group is mandala coloring. There is no intervention in the control group.

Main outcome variables
anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231126060181N1**
Registration date: **2024-02-03, 1402/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-03, 1402/11/14**
Update count: **0**

Registration date
2024-02-03, 1402/11/14

Registrant information

Name
Fatemeh Hasani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3477 2242

Email address
f.hasani@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-05, 1402/10/15

Expected recruitment end date
2024-02-04, 1402/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of mandala coloring on anxiety and pain in patients undergoing bone marrow biopsy

Public title
The effect of Manda staining on biopsy pain and anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in research. Be in the age range of 18 to 45 years. To undergo bone marrow sampling for the first time. Based on the Spielberger anxiety questionnaire, the research unit has mild or moderate anxiety. To treat pain and anxiety, they have not taken medicine or are not undergoing therapeutic intervention. Bone marrow sampling of the research units should be performed by a single physician. Sampling is done from the iliac region.

Exclusion criteria:
Unwillingness to participating in the intervention Receiving painkillers and anti-anxiety drugs Being under 18 years old or over 45 years old Lack of mental health

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization method is used to make sure that exactly equal number of participants enter the intervention and control groups in consecutive time intervals. The process of randomly dividing participants into different groups is called block randomization. Randomization gives every participant an equal chance to be placed in each of the groups. 4 blocks including 2 participants in the intervention group (B) and 2 participants in the control group (A) have been used, based on the sequence of entry and according to the block pattern that is randomly selected among the blocks AABB, ABBA, ABAB, BABA, BAAB are selected and assigned to intervention and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, people are divided into control and intervention groups, in the intervention group, people receive a type of intervention, and at the end, the control and intervention groups will be compared.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of arak University of Medical Sciences

Street address
Yas Alley، Jahangiri Street ،Imam Street

City
arak

Province
Markazi

Postal code
3816637677

Approval date
2023-12-03, 1402/09/12

Ethics committee reference number
IR.ARAKMU.REC.1402.188

Health conditions studied

1

Description of health condition studied
Pain and anxiety

ICD-10 code
F45.4

ICD-10 code description
Persistent somatoform pain disorder

Primary outcomes

1

Description
The anxiety score of the people is from the Spielberger questionnaire, which will be measured before the intervention, after the intervention, and after sampling.

Timepoint
Before intervention and ten minutes after sampling

Method of measurement
Spielberger anxiety questionnaire

Secondary outcomes

1

Description
Pain score of patients

Timepoint
بعد از نمونه برداری مغز استخوان

Method of measurement

Numerical pain rating scale

Intervention groups

1

Description
Intervention group: The only intervention performed in this group consists of coloring the same pattern copied in patients undergoing bone marrow sampling with 6-color ink made in Iran, for 30 minutes before the start of bone marrow sampling.
Category
N/A

2

Description
"Control group:" No intervention is done in this group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Khansari Hospital
Full name of responsible person
Fatemeh Hasani
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Yas Alley, Jahangiri St., Imam St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Davood Hekmatpo
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Arak University of Medical Sciences ,Basij Square, Arak Town
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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
Fatemeh Hasani
Position
Student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The data is accessible to all researchers.

Under which criteria data/document could be used

There are no conditions for using the data.

From where data/document is obtainable

To the researcher named Fatemeh Hasani with email address f.hasani@arakmu.ac.ir

What processes are involved for a request to access data/document

Almost two months

Comments