

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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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f.hasani@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpo

Street address

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

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity
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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