Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessing the effectiveness of melatonin compared to placebo in reducing pain and anxiety caused by bone marrow aspiration/biopsy in hematological patients: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim
Determining the effectiveness of melatonin on pain and anxiety in hematological patients undergoing bone marrow aspiration/ biopsy (BMAB)

Design
This study is a single-center, randomized, placebo-controlled clinical trial, which is conducted on 146 patients in two groups, placebo and melatonin drug group. Balance Blocked Randomization method and Stata software will be used for randomization.

Settings and conduct
The research team, including researchers, doctors, nurses, patients and statistical analysts, are not aware of the type of medicine received. Half an hour after receiving the drug and placebo, the patients will undergo BMAB and the patients will be evaluated for vital signs, occurrence of side effects, level of anxiety, intensity of the patient's pain, remaining pain level one month later, patient's memory and patient consent.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years;Definite or possible diagnosis of hematologic malignancy with indication for performing BMAB; Normal functional status (in the form of points 0 to 2 from ECOG). Exclusion criteria: Known allergy to melatonin or any of the product's components; the patient has not received melatonin medicine in the; Patients treated with analgesics or anti-anxiety drugs; Known patients with anxiety or psychotic disorders

Intervention groups
In the intervention group, each participant was administered melatonin at a dose of 10 mg orally, in addition to local anesthetic, 30 minutes before the start of the bone marrow biopsy. In the control group, each participant was administered placebo at a dose of 10 mg orally, in addition to local anesthetic, 30 minutes before the start of the bone marrow biopsy.

Main outcome variables
Intensity of pain; anxiety intensity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20140818018842N48**
Registration date: **2025-04-15, 1404/01/26**
Registration timing: **prospective**

Last update: **2025-04-15, 1404/01/26**
Update count: **0**

Registration date
2025-04-15, 1404/01/26

Registrant information

Name
Leyla Sharifi Aliabadi

Name of organization / entity
Research Institute for Hematology, Oncology and Stem Cell Transplantation,Tehran University of Medic

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-21, 1404/02/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of melatonin compared to placebo in reducing pain and anxiety caused by bone marrow aspiration/biopsy in hematological patients: A randomized, double-blind, placebo-controlled clinical trial

Public title

The effectiveness of melatonin in reducing pain and anxiety caused by bone marrow sampling

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Definitive or probable diagnosis of hematological malignancy with the indication of performing BMAB Normal functional status (in the form of points 0 to 2 from ECOG) Consciously to enter the study

Exclusion criteria:

Known allergy to melatonin or any of the product's components History of recent daily use of melatonin (the patient has not received melatonin medicine in the 72 hours before the study) Inability to swallow oral medication Known or suspected mal absorption or gastrointestinal obstruction The presence of moderate-intensity uncontrolled pain (controlled pain is defined as no change in pain intensity or a change in the patient's pain medication in the last 48 hours) Patients treated with analgesics or anti-anxiety drugs Known patients with anxiety or psychotic disorders Patients with drug or nicotine addiction Pregnancy or breastfeeding Patient participation in another research project at the same time

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Melatonin and placebo in the form of completely identical oral tablets will be produced by the pharmaceutical company and will be provided to the research team (third party). Balance Blocked Randomization method and Stata software will be used for randomization. Random allocation is done using blocks of size 4. In this way, using the ralloc module (Random allocation of treatments in controlled trials) in Stata software, random samples are determined for study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The randomization sequence is prepared by a statistician who has no connection with the patients. Melatonin and placebo will be produced by the pharmaceutical company in completely identical appearance and will be provided to the research team (third pateint). The researchers and participants will be unaware of which tablet is the drug and which is the placebo. After confirming the entry of a new patient into the study and registering the patient code, the coordinator who is stationed at the patient registration site will place the patient in one of the study groups based on the specified randomization sequence, and the drugs that are labeled with the specified code Each patient provides them.

Placebo

Used

Assignment

Other

Other design features

All study participants will receive the same treatments based on existing protocols. BMAB will be performed in the study participants with the same method and by a common physician and assistant. After entering the study, patients are randomly divided into drug and placebo groups. In addition to the local anesthetic, melatonin with a dose of 10 mg or placebo is administered orally to each participant 30 minutes before the start of bone marrow sampling. Each patient will be included in the study only once, even if multiple BMABs are needed

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Institute of Pharmaceutical Sciences, Tehran University of Medical Scie

Street address

Research Center for Pharmaceutical Sciences, Faculty of Pharmacy, Porsina Street

City

Tehran

Province

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Postal code

1417614411

Approval date

2024-10-12, 1403/07/21

Ethics committee reference number

IR.TUMS.TIPS.REC.1403.128

Health conditions studied

1

Description of health condition studied

hematologic malignancy

ICD-10 code

C96.9

ICD-10 code description

Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified

Primary outcomes

1

Description

Pain intensity in the visual analogue scale

Timepoint

Pain intensity immediately, 30 minutes, and then the day after the bone marrow biopsy

Method of measurement

By using a visual analogue scale questionnaire

2

Description

Anxiety severity using the Speilberger State–Trait Anxiety Inventory questionnaire

Timepoint

Patient's anxiety level 5 minutes before BMAB

Method of measurement

by using Speilberger State–Trait Anxiety Inventory questionnaire

Secondary outcomes

1

Description

The amount of painkillers required to reduce pain, the total dose of painkillers (including opioids, acetaminophen, and NSAIDs) used after BMAB in each patient

Timepoint

Patients are monitored for 24 hours after the end of BMAB

Method of measurement

Patient's record

2

Description

The need for sedatives to reduce anxiety

Timepoint

Patients are monitored for 24 hours after the end of BMAB

Method of measurement

By using patient record data

3

Description

The time required to administer the first dose of pain medication

Timepoint

Patients are monitored for 24 hours after the end of BMAB

Method of measurement

By using patient record data

4

Description

Time required to administer the first dose of a sedative

Timepoint

Patients are monitored for 24 hours after the end of BMAB

Method of measurement

By using patient record data

5

Description

Patient satisfaction with the procedure

Timepoint

The morning after BMAB

Method of measurement

The patient's level of satisfaction with the procedure is evaluated with the question "Are you willing to repeat the procedure with the same amount of pain reliever/anti-anxiety medication?" (yes/no). In this regard, if the answer to the satisfaction question is yes, the patient is considered "satisfied". Satisfaction with the procedure - yes - no

6

Description

Pain score on the visual analogue scale

Timepoint

One month after performing BMAB, the presence or absence of pain and then its intensity are recorded in patients

Method of measurement

By using visual analogues scale

7

Description

The memory of pain a month later

Timepoint

The patient's memory of the pain experience caused by BMAB is evaluated in a telephone call after one month Community Verified icon

Method of measurement

In this regard, if the answer to any of the three questions including "dreaming about this event", "feeling like running away from thinking about this event" and "feeling overwhelmed by thinking about this event", is yes, the memory of pain The patient is considered

"positive". Pain memory - yes - no

Intervention groups

1

Description
Intervention group: All study participants will receive the same treatments based on existing protocols. BMAB will be performed in the study participants with the same method and by a common physician and assistant. After entering the study, patients are randomly divided into drug and placebo groups. Each participant in the drug group was prescribed melatonin with a dose of 10 mg orally, 30 minutes before the start of bone marrow sampling, in addition to the local anesthetic. Each patient will be included in the study only once, even if multiple BMABs are needed.

Category
Treatment - Drugs

2

Description
Control group: ll study participants will receive the same treatments based on existing protocols. BMAB will be performed in the study participants with the same method and by a common physician and assistant. After entering the study, patients are randomly divided into drug and placebo groups. Each participant will be prescribed a placebo orally, 30 minutes before the start of bone marrow sampling, along with local anesthetic. Each patient will be included in the study only once, even if multiple BMABs are needed.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Hematology and Oncology

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Institute for Oncology, Hematology and Cell Therapy

Full name of responsible person
Mohammad Vaezi

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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
Research Institute for Oncology, Hematology and Cell Therapy

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
Tehran University of Medical Sciences

Full name of responsible person
Soma Rahimi

Position
Resident of Pharmacotherapy

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available