

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of Oxycodone plus Lidocaine plus Lorazepam in combination versus Lidocaine alone in pain induced by Bone marrow Aspiration and Biopsy (BMAB) in Mazandaran Cancer Center

Protocol summary

Study aim

Evaluation of the effect of Oxycodone plus Lidocaine plus Lorazepam in combination versus Lidocaine alone in pain induced by Bone marrow Aspiration and Biopsy

Design

Randomized two parallel group clinical trial with blinded outcome assessment

Settings and conduct

The study will be done in Imam Khomeini hospital of Sari. Forty patients will be included in each arm of the study. Patients, physicians and assessor will be blinded regarding grouping of the patients. Assignment to two arms of the study will be done using random digit table.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients older than 18 years (inpatient or outpatient) 2- Patients who are candidate for Bone Marrow Aspiration and Biopsy (BMAB) Exclusion criteria: 1- Mental disorder 2- Language problems 3- Unwillingness to participate in the study

Intervention groups

In one group, patients will receive only subcutaneous injection of lidocaine hydrochloride 1%, and in the other group, patients will be given tablet lorazepam (2 mg) and tablet oxycodone (10 mg) half an hour before BMAB and lidocaine as subcutaneous injection before BMAB.

Main outcome variables

1- Pain score based on visual analogue score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090613002027N13**
Registration date: **2018-08-04, 1397/05/13**
Registration timing: **prospective**

Last update: **2018-08-04, 1397/05/13**

Update count: **0**

Registration date

2018-08-04, 1397/05/13

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research and Technology deputy of Mazandaran University of Medical Sciences

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Oxycodone plus Lidocaine plus Lorazepam in combination versus Lidocaine alone in pain induced by Bone marrow Aspiration and Biopsy (BMAB) in Mazandaran Cancer Center

Public title

Effect of Oxycodone plus Lorazepam in pain induced by Bone marrow Aspiration and Biopsy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients older than 18 years (inpatient or outpatient)
Patients who are candidate for Bone Marrow Aspiration and Biopsy (BMAB) in Mazandaran Cancer Center

Exclusion criteria:

Mental disorder Language problems Unwillingness to participate in the study

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will enter the trial randomly based on the random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Assignment of patients to different groups of the study will be determined based on digit random table. Placebo of Oxycodone and Lorazepam will be prepared in the Faculty of Pharmacy of Sari. A unique Five-digit number will be assigned for each patient. The intervention (drug or placebo) will be put in the envelopes and the nurse of oncology division will give the intervention to the patients according to predetermined codes before Bone marrow aspiration/biopsy. The patient, physician and the assessor will be blinded regarding the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics Committee of mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, kilometer 18 of Farah Abad road, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2018-06-25, 1397/04/04

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.1703

Health conditions studied**1****Description of health condition studied**

bone marrow and aspiration biopsy related pain

ICD-10 code

T81.9

ICD-10 code description

Unspecified complication of procedure

Primary outcomes**1****Description**

Pain Score following bone marrow aspiration/biopsy

Timepoint

10 minutes following Bone marrow Aspiration and Biopsy

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

5ml lidocaine hydrochloride 1% during bone marrow aspiration and biopsy

Category

Treatment - Drugs

2**Description**

2mg lorazepam tablet 30 minutes before bone marrow aspiration and biopsy

Category

Treatment - Drugs

3

Description

10mg oxycodone tablet 30 minutes before bone marrow aspiration and biopsy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital of Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mazandaran 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

Faculty of Pharmacy, Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Position

Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Pharmacist

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Person responsible for updating data

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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
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
No - There is not a plan to make this available