Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
]nclusion 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

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Ebrahim Salehifar

Name of organization / entity
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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 Scienses, 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
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Full name of responsible person
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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
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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