Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the efficacy of intravenous Labetalol and the usual method (local anesthesia) on pain controlling and anxiety during bone marrow aspiration and biopsy

Protocol summary

Study aim
Evaluation of the efficacy of intravenous labetalol in comparison with the conventional method (local anesthesia) on pain control during bone marrow aspiration and biopsy

Design
A randomized, double blind, sham controlled clinical trial. 40 patients who are candidates for bone marrow aspiration and biopsy will be randomly divided into two intervention (intravenous Labetalol) and control groups.

Settings and conduct
Participants are patients who are candidates for bone marrow aspiration and biopsy who referred to the oncology ward of Semnan Kowsar Hospital.Patients will be randomly assigned to either the labaletol and control groups.The researcher and patient will be unaware of the grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: over 18 years of age, definitive indication for bone marrow aspiration and biopsy.
Exclusion criteria: unwillingness to participate in study, cardiovascular disease (heart block, arrhythmia), uncontrolled chronic obstructive pulmonary disease, uncontrolled asthma, hypotension, consciousness disorder, bradycardia, pregnancy and lactation, using analgesics for the past 24 hours, elderly people with advanced systemic disease

Intervention groups
Patients in the intervention group will receive IV labetalol (5mg) in addition to Fentanyl and anesthesia. Patients in the control group will receive local anesthesia, Fentanyl and placebo.

Main outcome variables
Pain intensity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191201045563N1**
Registration date: **2020-01-05, 1398/10/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-05, 1398/10/15**
Update count: **0**

Registration date
2020-01-05, 1398/10/15

Registrant information
Name
Masoudeh Darzi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 3325 9150
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-12-06, 1398/09/15
Expected recruitment end date
2020-02-04, 1398/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of intravenous Labetalol and the usual method (local anesthesia) on pain controlling and anxiety during bone marrow aspiration and biopsy

Public title
The efficacy of intravenous Labetalol on pain controlling and anxiety during bone marrow aspiration and biopsy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age more than 18 years old Definitive indication of bone marrow aspiration and biopsy

Exclusion criteria:
Unwillingness to participate in the study Cardiovascular disease (Heart block, Arrhythmia) Uncontrolled chronic obstructive pulmonary disease Uncontrolled Asthma Unstable hemodynamics especially hypotension, bradycardia Consciousness disorder Pregnancy and lactation Bad physical conditions Using analgesic agents for the past 24 hours Elderly people with advanced systemic disease Vertigo, headache, dyspnea, nausea before the procedure

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple random method using random numbers table; with the help of someone other than the researcher, the sealed packets are prepared, on which the numbers are placed behind each other, in which the intervention or control group is determined according to the random number table. And the numbers are used for patients in the study, respectively.Thus, each patient is accidentally in the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Study participants, principal investigator and Statistical analyzer;The drug used in the control and intervention groups is administered by a person other than the principal investigator, the clinical caregiver. the results of the data are presented in the form of groups called 1 and 2 to statistical classifiers.Although patients are given the necessary knowledge of the study and informed consent is obtained, they will not be informed about the group in which they are participating.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Headquarters building of Semnan University of Medical Sciences, Basij blvd., Moallem Square

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2019-11-23, 1398/09/02

Ethics committee reference number
IR.SEMUMS.REC.1398.203

Health conditions studied

1

Description of health condition studied
Bone Marrow Aspiration and Biopsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain intensity based on 10cm visual analogue scale(VAS)

Timepoint
During the procedure, 5 minutes and one hour after the procedure

Method of measurement
10cm visual analogue scale (VAS)

Secondary outcomes

1

Description
Anxiety score

Timepoint
30 minutes before starting the procedure and during the procedure

Method of measurement

Clinical Anxiety-Depression Self-Assessment Scale (HADS)

2

Description
Amount of opioids used during the procedure and within 24 hours after the procedure
Timepoint
During the procedure, up to 24 hours after the procedure
Method of measurement
Record the amount of drug used in each patient

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive IV labetalol (5mg) in addition to fentanyl and anesthesia.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group will receive local anesthesia, fentanyl and placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Masoudeh Darzi
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Kosar hospital, Amin blvd, Golestan town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
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?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Masoudeh Darzi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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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
No more 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
Undecided - It is not yet known if there will be 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