

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 labetalol 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

Email address

masoudehdarzi@semums.ac.ir

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 analyster

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

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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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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