Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Determining and comparing the effectiveness of intravenous injection of apotel, promethazine syrup and local anesthesia with intravenous injection of pethidine and local anesthesia in controlling pain in patients candidate for bone marrow aspiration and biopsy.

Protocol summary

Study aim

Evaluation and comparison of analgesic effect of intravenous apotel, promethazine syrup and local anesthesia with intravenous pethidine injection and local anesthesia in bone marrow biopsy

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 44 patients. Random allocation software was used for randomization

Settings and conduct

The lidocaine injection and BMA / B process is performed by a hematologist-oncologist for all subjects. The nurse and physician who perform the procedure, as well as the patient, are unaware of the code assignment. In this study, physician, patient and nurse are blind to the study

Participants/Inclusion and exclusion criteria

Inclusion criteria Age 18 -55 years Conscious consent to enter the study Exclusion criteria Mental inability to express pain

Intervention groups

Case group: 1. Infusion of 1 gram apotel in 100 cc of normal saline half an hour before the procedure 2. Promethazine syrup (25 mg) 30 minutes before the procedure 3. Intravenous injection of 1 cc normal saline fifteen minutes before the procedure 4.Topical injection of 10 cc of 1% lidocaine, 3 minutes before the procedure Control group: 1.Infusion of 100 cc of normal saline serum half an hour before the procedure 2.Five cc of colored syrup without medication 30 minutes before the procedure 3.Intravenous injection of pethidine (25 mg) 15 minutes before the procedure 4.Topical injection of 10 cc of 1% lidocaine, 3 minutes before the procedure

Main outcome variables

A questionnaire is prepared for each patient in advance and is given to the patient after the procedure. This questionnaire includes the following two questions: 1. After the procedure and 30 minutes later, the patient's pain is estimated 2. Anxiety: After the procedure and 30 minutes after that, the patient's level of anxiety is ranked from 1 to 10, depending on the severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047215N2**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **prospective**

Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

Ali Darakhshandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3777 2640

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining and comparing the effectiveness of intravenous injection of apotel, promethazine syrup and local anesthesia with intravenous injection of pethidine and local anesthesia in controlling pain in patients candidate for bone marrow aspiration and biopsy.

Public title

Pain control in bone marrow aspiration and biopsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-55 years Conscious consent to enter the study BMI 18-25

Exclusion criteria:

Mental retardation Generalized anxiety disorder Major Depressive Disorder Pregnancy Lactation Drug addiction Take analgesic less than 4 hours before admission Hypersensitivity to apotel, promethazine and lidocaine GFR < 30 Cirrhosis Child B & C

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with confirmed inclusion criteria are selected through easy sampling and are placed in case or control group with random allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, the main researcher, the physician and the nursing staff are kept blind to the allocation of study groups. The lidocaine injection and BMA / B process is performed by a hematologist-oncologist for all subjects. The nurse and physician who perform the injection and the procedure, as well as the patient, are unaware of the patient group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No 566,Saadat Ave, Molana Blvd, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174797677

Approval date

2020-12-12, 1399/09/22

Ethics committee reference number

IR.MUI.MED.REC.1399.817

Health conditions studied

1

Description of health condition studied

Bone marrow disease

ICD-10 code

C90

ICD-10 code description

Multiple myeloma and malignant plasma cell neoplasms

Primary outcomes

1

Description

Reduction of pain during bone marrow biopsy and aspiration

Timepoint

Immediately after completing the procedure and 30 minutes later in the intervention and control groups

Method of measurement

To estimate the severity of pain and the effect of the drug in relieving the patient's pain from the quantitative scale VAS(Visual Analog Scale) is used.

2

Description

Anxiety after completing the procedure

Timepoint

After the procedure and 30 minutes later, the patient's anxiety is rated from 1 to 10, depending on the severity.

Method of measurement

Anxiety severity is divided from zero to ten using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1. Infusion of one gram ampoule in 100 cc of normal saline serum half an hour before the procedure 2. 5 cc of promethazine syrup (25 mg) 30 minutes before the procedure 3. Intravenous injection of 1 cc ampoule containing normal saline fifteen minutes before the procedure 4. Topical injection of 10 cc of 1% lidocaine, 3 minutes before the procedure

Category
Treatment - Drugs

2

Description
Control group: 1. Infusion of 100 cc of normal saline serum half an hour before the procedure 2.Five cc of colored syrup without medication 30 minutes before the procedure 3. Intravenous injection of 25 mg of pethidine 15 minutes before the procedure 4. Topical injection of 10 cc of 1% lidocaine, 3 minutes before the procedure

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid Hospital.Isfahan

Full name of responsible person
Ali Darakhshandeh

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No 566, 13 Alley, Saadat streat, Janbazan Blvd, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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http://med.mui.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Ali Darakhshandeh

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology and Medical Oncology

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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
There is no more information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Start of access period of the year 1400
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Information will be shared if applicants make their request clear and explicit
From where data/document is obtainable
Request by email with the designer of the study
What processes are involved for a request to access data/document
If we receive an email to receive information; The application will be reviewed by the study planners and emailed to them if there is no prohibition.
Comments