Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Study of Oral Ibuprofen Effect on Pain , anxiety and Physiological Indexes in Patients Undergoing Bone marrow Biopsy in kowsar hospital from 2019 to 2020

Protocol summary

Study aim
) Comparison of the effect of oral ibuprofen on pain relief in patients undergoing bone marrow biopsy considering age, sex and body mass index 2) Comparison of the effect of oral ibuprofen on reducing anxiety in patients undergoing bone marrow biopsy considering age, sex and body mass index 3) Determining the effect of oral ibuprofen on systolic and dyastolic blood pressure , heart rate and blood oxygen in patients during and after bone marrow biopsy or aspiration

Design
Clinical trial, with control group, one-way blind, randomized

Settings and conduct
The study was performed in the oncology ward of Kowsar Hospital. In both groups, biopsy and aspiration of the bone marrow from the superior posterior iliac spine were performed. Injected. Medication was given to patients. Pain questionnaire. Anxiety was filled by the patient and physiological indicators were recorded.

Participants/Inclusion and exclusion criteria
No entry: taking sedative drug and opioid, History of hypersensitivity reactions to non-steroidal anti-inflammatory drugs , Third trimester of pregnancy or lactation Brain bleeding, active bleeding ,uncontrolled heart failure ، thrombocytopenia entrance : more than 18 years old full satisfaction

Intervention groups
Intervention group: An hour before the procedure will receive a 400-mg oral ibuprofenic tablet

Main outcome variables
Reducing pain and anxiety Bone marrow biopsy pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181009041284N1**
Registration date: **2020-09-28, 1399/07/07**
Registration timing: **retrospective**

Last update: **2020-09-28, 1399/07/07**
Update count: **0**

Registration date
2020-09-28, 1399/07/07

Registrant information

Name
Fateme Mohammadkhani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-10, 1398/12/20

Expected recruitment end date
2020-05-14, 1399/02/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Study of Oral Ibuprofen Effect on Pain , anxiety and Physiological Indexes in Patients Undergoing Bone

marrow Biopsy in kowsar hospital from 2019 to 2020

Public title
Effect of Oral Ibuprofen in Bone Marrow Biopsy Pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Satisfaction of the patient to participate in the plan Compelete consciousness Be in the adult age category (over 18 years old)
Exclusion criteria:
Taking sedative drug and opioid History of asthma, urticaria, and any hypersensitivity reactions to non-steroidal anti-inflammatory drugs and aspirin Pacemaker Third trimester of pregnancy or lactation Active liver disease Brain bleeding or other active bleeding Uncontrolled heart failure Inflammatory bowel disease Thrombocytopenia
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed by simple randomization method. Numbers from 1 to 30 were written on paper and placed in sealed envelopes. It was then distributed among the samples and patients who had even numbers in the envelope were in the intervention group and those who had odd numbers were in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
All patients were kept blind. Because the control group was given a drug very similar to Ibuprofen.
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
Kosar hospital , Amin blvd, Golestan town , Semnan City
City
Semnan
Province
Semnan
Postal code
3519899951
Approval date
2020-02-23, 1398/12/04
Ethics committee reference number
IR.SEMUMS.REC.1398.293

Health conditions studied

1

Description of health condition studied
Pain and anxiety and physiological parameters during bone marrow biopsy and aspiration
ICD-10 code
D75.9
ICD-10 code description
Disease of blood and blood-forming organs, unspecified

Primary outcomes

1

Description
Pain score at visual analogue scale questionnaire
Timepoint
After the end of the procedure
Method of measurement
Visual analogue scale questionnaire

2

Description
Anxiety score at clinical Global Impression questionnaire
Timepoint
After the end of the procedure
Method of measurement
Clinical Global Impression questionnaire

3

Description
The amount of blood pressure
Timepoint
Before the intervention, the second minute, the fourth minute, the end of the intervention
Method of measurement
Mercury sphygmomanometer

4

Description
Heart rate
Timepoint
Before the intervention, the second minute, the fourth

minute, the end of the intervention

Method of measurement

Cardiac monitoring device

5

Description

Percentage of blood oxygen saturation

Timepoint

Before the intervention, the second minute, the fourth minute, the end of the intervention

Method of measurement

Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:One hour before the procedure, the patient receives one 400 mg ibuprofen tablet orally. The number of drugs is one and a single dose.This method of drug therapy is to reduce pain and is a non-steroidal anti-inflammatory drug and is done only once. The manufacturer is Abaidi.

Category

Treatment - Drugs

2

Description

Control group: One hour before the procedure, they receive a placebo similar to ibuprofen 400 mg tablet. This pill has no therapeutic effects and looks similar to ibuprofen. It is taken orally and once.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan Kosar Hospital

Full name of responsible person

Mohammad Foroozesh Fard

Street address

Kosar Hospital , Amin Blvd, Golestan,Town , Semnan City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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Web page address

http://www.semums.ac.ir

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

Mohammad Foroozesh Fard

Position

Proffesor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact
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Mohammad Foroozesh Fard
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
-All data and results can be shared after the study
When the data will become available and for how long
-Will be available in December.
To whom data/document is available
Only available to scholars working in academic institutions.
Under which criteria data/document could be used
In case of relevant studies.
From where data/document is obtainable
Rozita Hedayati. Neuromuscular Rehabilitation Research Center, Ghods Blvd. +98 912 331 1988
What processes are involved for a request to access data/document
After making the necessary edits, these documents will be registered in the form of articles and will be available at December
Comments
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