

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

1) 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 diastolic 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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+98 23 3346 6945

Email address

medc855@yahoo.com

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		Street address Kosar hospital , Amin blvd, Golestan town , Semnan City	
Public title	Effect of Oral Ibuprofen in Bone Marrow Biopsy Pain	City	Semnan
Purpose	Supportive	Province	Semnan
Inclusion/Exclusion criteria	Inclusion criteria: Satisfaction of the patient to participate in the plan Complete 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	Postal code	3519899951
Age	From 18 years old	Approval date	2020-02-23, 1398/12/04
Gender	Both	Ethics committee reference number	IR.SEMUMS.REC.1398.293
Phase	3	Health conditions studied	
Groups that have been masked	Participant	1	
Sample size	Target sample size: 30	Description of health condition studied	Pain and anxiety and physiological parameters during bone marrow biopsy and aspiration
Randomization (investigator's opinion)	Randomized	ICD-10 code	D75.9
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.	ICD-10 code description	Disease of blood and blood-forming organs, unspecified
Blinding (investigator's opinion)	Single blinded	Primary outcomes	
Blinding description	All patients were kept blind. Because the control group was given a drug very similar to Ibuprofen.	1	
Placebo	Used	Description	Pain score at visual analogue scale questionnaire
Assignment	Parallel	Timepoint	After the end of the procedure
Other design features		Method of measurement	Visual analogue scale questionnaire
Secondary Ids	empty	2	
Ethics committees		Description	Anxiety score at clinical Global Impression questionnaire
1		Timepoint	After the end of the procedure
Ethics committee		Method of measurement	Clinical Global Impression questionnaire
Name of ethics committee	Ethics committee of Semnan University of Medical Sciences	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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3519899951

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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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Email

P_Kokha@yahoo.com

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

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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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