

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

comparison of the efficacy and complication of two medication regimen 'naproxen and loratadin' with 'acetaminophen and loratadin' on relief of bone pain due to PEG G-CSF in patients with solid tumors chemotherapy

Protocol summary

Study aim

Reducing the amount of pain in neutropenic cancer patients and improving the quality of life, and making it easier to continue treatment with a less complicated drug like Acetaminophen for these patients.

Design

Clinical trial, simple randomized with block method with statistical software, with parallel groups with a sample size of 100 in each group (200 in total), trial phase 3

Settings and conduct

Patients include people with solid tumor or lymphoma who are candidates for PEGG-CSF after chemotherapy based on valid chemotherapy protocol and refer to the Imam Hossein Hospital chemotherapy center in Tehran. The method of this study was to fill the pain questionnaire before, during and after treatment with PEG G-CSF by patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with solid tumor or lymphoma Candidate for receiving PEG G-CSF after chemotherapy based on well known chemotherapy protocol. Exclusion criteria: Bone metastasis CKD or ESRD Patients receiving chemotherapy drugs that have bone pain are a high prevalence of 10% (TAXAN family, bisphosphonate ...) Pathologic fracture or fracture due to any reason Vitamin D level less than 20

Intervention groups

A group treated with acetaminophen and loratadine A group treated with naproxen and loratadine

Main outcome variables

Amount of pain in the group treated with Acetaminophen and Loratadine Complications of acetaminophen and loratadine group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190514043586N1**

Registration date: **2019-05-31, 1398/03/10**

Registration timing: **prospective**

Last update: **2019-05-31, 1398/03/10**

Update count: **0**

Registration date

2019-05-31, 1398/03/10

Registrant information

Name

seyyed saeid noorani yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3521 0445

Email address

s.noorani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the efficacy and complication of two

medication regimen 'naproxen and loratadin' with 'acetaminophen and loratadin' on relief of bone pain due to PEG G-CSF in patients with solid tumors chemotherapy

Public title

Effect of Acetaminophen on relief of bone pain due to PEG G-CSF

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with Solid Tumor or Lymphoma who receive PEG G-CSF due to neutropenia after chemotherapy

Exclusion criteria:

Bone metastasis PFS more than 2 Osteomalacia proven with laboratory tests CKD or ESRD Active Rheumatologic disease Uncontrolled Diabetes or Thyroid disease Patients receiving chemotherapy drugs that have bone pain are a high prevalence of 10% (TAXAN family, bisphosphonate ...) Pathologic fracture or fracture due to any reason Naproxen use contraindication Vitamin D level less than 20 Paget disease Hyperparathyroidism People who have had a score of over 6 in the bone pain score since the beginning of the project Liver disease History of Cardiac Arrhythmia Patient who have not compliance for completing pain questionnaire

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are selected through available sampling method and are assigned to one of the two treatment groups using a simple accident method with blocks with block size 2. In this method, by referring each patient to the clinic, a card of size 2 will be taken randomly by the researcher and, depending on how the order is written on the card, the patient is assigned to group 1 or 2. The randomization unit here is the person participating in the study and there is no layer randomization. The randomization tool is a ready-made card that the researcher randomly takes them and ensures a random sequence of people entering the study. Hiding for the patient and researcher is not applicable here, but for the statistical analyst, hiding is carried out, and the data for the two groups of patients are presented to him as groups A and B.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-Chancellor in Research Affairs-Shahid Beheshti University of Medical Sciences

Street address

13th floor, block A, Central staff of Ministry of Health and Medical Education, Simaye Iran Ave., between south Falamak and Zarafshan AVE., Qods(gharb) town

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Province

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Postal code

1615633156

Approval date

2019-04-14, 1398/01/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.010

Health conditions studied**1****Description of health condition studied**

Bone Pain Due to PEG G-CSF

ICD-10 code

C83

ICD-10 code description

Non-follicular lymphoma

Primary outcomes**1****Description**

Pain Score in Visual Analogue Scale(VAS) questionnaire

Timepoint

Day 0; One day after the end of first and third course of chemotherapy

Method of measurement

Visual Analogue Scale questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1:Tab Acetaminophene 500 mg orally

every 6 hours +Tab Loratadine 10 mg orally daily, from Kimidarou manufacturer, duration of drug use is from pain onset to 48 hours after pain relief.

Category

Treatment - Drugs

2

Description

Intervention group2: Tab Naproxene 500 mg orally every 12 hours +Tab Loratadine 10 mg orally daily,from Kimidarou manufacturer, duration of drug use is from pain onset to 48 hours after pain relief.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein hospital

Full name of responsible person

Seyed Saeid Noorani Yazdi

Street address

South Shahid Madani Ave., Emam Hossein Hospital

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dr.saeid.noorani@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University Of Medical Science, Arabi Ave., Yaman Ave., Chamran Highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Amir Sheykholeslami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

No more information

When the data will become available and for how long

One Year After Publish of Results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For studying and treating patients

From where data/document is obtainable

E-mail: dr.saeid.noorani@gmail.com

What processes are involved for a request to access data/document

Sign in to the clinical trial site and search for keywords

Comments