Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Investigating and comparing the effect of three therapeutic methods of Naproxen, hydroxyzine and Syrup Noscough as therapeutic methods for treatment of the bone pain caused by granulocyte-colony stimulating factor(GCSF) in cancer patients

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

Design
Clinical trial, simple randomized with block method with statistical software, with parallel groups with a sample size of 41 in each group (123in total), trial phase 3

Settings and conduct
Patients include people with solid tumor or lymphoma who are candidates for pegfilgrastim 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 pegfilgrastim by patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with solid tumor or lymphoma Candidate for receiving pegfilgrastim after chemotherapy based on well known chemotherapy protocol. Exclusion criteria: Bone matastasis chronic kidney disease or end stage renal 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 Vitamin D level less than 20

Intervention groups
Control group 1: Hydroxyzine 25 mg orally daily" from the manufacturer of Kimidaru and the duration of use is considered from the onset of pain for 5 days in each of the first 4 cycles of chemotherapy. Control group 2: naproxen 500 mg every 12 hours orally "Chemidaru manufacturer and duration of use from the onset of pain for 5 days in each of the first 4 cycles of chemotherapy is considered. The target intervention group (main): noscough syrup 15 cc daily orally, manufactured by Faran Chemi, and the duration of use is considered from the onset of pain for 5 days in each of the first 4 cycles of chemotherapy

Main outcome variables
Amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231227060538N1**
Registration date: **2024-03-04, 1402/12/14**
Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**
Update count: **0**

Registration date
2024-03-04, 1402/12/14

Registrant information

Name
Fatemeh Talebian taheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4601 5120

Email address
fatimatalebian@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-20, 1403/01/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the effect of three therapeutic methods of Naproxen, hydroxyzine and Syrup Noscough as therapeutic methods for treatment of the bone pain caused by granulocyte-colony stimulating factor(GCSF) in cancer patients

Public title

Investigating and comparing the effect of three therapeutic methods of Naproxen, hydroxyzine and Syrup Noscough as therapeutic methods for preventing bone pain caused by granulocyte-colony stimulating factor(GCSF)in cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: patients with solid tumor or lymphoma Candidate for receiving Pegfilgrastim -after chemotherapy based on well known chemotherapy protocol

Exclusion criteria:

Bone metastasis in patients with progression free survival(PFS)greater than 2 Test-proven osteomalacia chronic kidney disease or end stage renal disease patients Patients with active rheumatic disease diabetes Uncontrolled thyroid disease Patients receiving chemotherapy drugs in which bone pain is one of the complications with a high incidence of 10% (TAXAN family, bisphosphonate.) Patients with pathological fracture or fracture due to any other reason Opioid addicts Contraindications for taking naproxen and methadone and other similar drugs Vitamin D level less than 20 Paget's disease Hyperparathyroid disease Patients who have bone pains in the questionnaire with a score above 6 since the beginning of the project liver disease Patients with a history of cardiac arrhythmia Patients who do not have the appropriate admission to fill out the pain questionnaire

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

All eligible subjects will be randomly assigned to one of the three groups receiving noscough, hydroxyzine, and naproxen with a ratio of 1:1:1. The randomization will be in the form of permuted block randomization, with 13 blocks based on the sample size in sizes 3, 6, 9, 12, 15 until the sample size is completed using the "Ralloc" package in STATA software. Patients will be included in each group based on the determined sample size and based on the list of randomized individuals (along with a specific research code for each individual).

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

The Ethics Committee of the Research and Technology Vice-Chancellor of Shahid Beheshti University of

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

City

Tehran

Province

Tehran

Postal code

1615633156

Approval date

2024-02-26, 1402/12/07

Ethics committee reference number

IR.SBMU.MSP.REC.1402.617

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
One day after the end of the first, second, third and fourth course of chemotherapy
Method of measurement
Visual Analogue Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The target intervention group (main): noscough syrup 15 cc daily orally, manufactured by Faran Chemi factory, and the duration of use is considered from the onset of pain for 5 days in each of the first 4 cycles of chemotherapy
Category
Treatment - Drugs

2

Description
Intervention group:Naproxen 500 mg orally every 12 hours "Chemidaru manufacturer and duration of use from the onset of pain for 5 days in each of the first 4 cycles of chemotherapy is considered.
Category
Treatment - Drugs

3

Description
Intervention group:"Hydroxyzine 25 mg daily orally" manufactured by Kimidaro and the duration of use is considered from the onset of pain for 5 days in each of the first 4 cycles of chemotherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hossein hospital
Full name of responsible person
Fatemeh Talebian Taheri
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South Shahid Madani Ave., Emam Hossein Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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1983969411
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sci@sbmu.ac.ir
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
Fatemeh Talebian Taheri
Position
Student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Email
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https://ehmc.sbmu.ac.ir

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All patient information will be entered into the database (Excel format) and after checking the the outliers terms and data cleaning, it will be prepared for statistical analysis. The final data file will be provided to the research unit of internal diseases department to conduct further studies.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers in academic institutions
Under which criteria data/document could be used
If there is a positive outcome and to need for further studies in this field
From where data/document is obtainable
Dr. Fatemeh Talebian Taheri-Imam Hossein Hospital-internal disease clinics Address:South Shahid Madani Ave., Emam Hossin hospital Postal code 1617763141 Phone: 02173430000 email: fatimatalebian@ymail.com Web page address: https://ehmc.sbmu.ac.ir
What processes are involved for a request to access data/document
Through the written request of the applicant to the research department of Imam Hossein Hospital And after confirming and signing the memorandum of understanding, the data will be available to the applicant within two months.
Comments