

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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 metastasis 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)

##### Phone

+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

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| <div>2024-05-21, 1403/03/01</div> <div>Actual recruitment start date</div> <div>empty</div> <div>Actual recruitment end date</div> <div>empty</div> <div>Trial completion date</div> <div>empty</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <div>Scientific title</div> <div>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</div> <div>Public title</div> <div>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</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <div>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).</div> <div>Blinding (investigator's opinion)</div> <div>Not blinded</div> <div>Blinding description</div> <div>Placebo</div> <div>Not used</div> <div>Assignment</div> <div>Parallel</div> <div>Other design features</div> <div>Secondary Ids</div> <div>empty</div>                                                                                                                                                                                                                          |
| <div>Purpose</div> <div>Treatment</div> <div>Inclusion/Exclusion criteria</div> <div>Inclusion criteria:</div> <div>Inclusion criteria: patients with solid tumor or lymphoma Candidate for receiving Pegfilgrastim -after chemotherapy based on well known chemotherapy protocol</div> <div>Exclusion criteria:</div> <div>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</div> | <div>Ethics committees</div> <div>1</div> <div>Ethics committee</div> <div>Name of ethics committee</div> <div>The Ethics Committee of the Research and Technology Vice-Chancellor of Shahid Beheshti University of</div> <div>Street address</div> <div>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</div> <div>City</div> <div>Tehran</div> <div>Province</div> <div>Tehran</div> <div>Postal code</div> <div>1615633156</div> <div>Approval date</div> <div>2024-02-26, 1402/12/07</div> <div>Ethics committee reference number</div> <div>IR.SBMU.MSP.REC.1402.617</div> <div>Health conditions studied</div> <div>1</div> <div>Description of health condition studied</div> <div>Bone Pain Due to PEG G-CSF</div> <div>ICD-10 code</div> <div>C83</div> <div>ICD-10 code description</div> <div>Non-follicular lymphoma</div> |
| <div>Age</div> <div>No age limit</div> <div>Gender</div> <div>Both</div> <div>Phase</div> <div>3</div> <div>Groups that have been masked</div> <div>No information</div> <div>Sample size</div> <div>Target sample size: 123</div> <div>Randomization (investigator's opinion)</div> <div>Randomized</div> <div>Randomization description</div> <div>All eligible subjects will be randomly assigned to one of the three groups receiving noscough, hydroxyzine, and</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <div>Primary outcomes</div> <div>1</div> <div>Description</div> <div>Pain Score in Visual Analogue Scale(VAS) questionnaire</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

**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

**Street address**

South Shahid Madani Ave., Emam Hossein Hospital

**City**

Tehran

**Province**

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1617763141

**Phone**

+98 21 7343 0000

**Email**

fatimatalebian@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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**Province**

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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**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

South Shahid Madani Ave., Emam Hossin hospital

**City**

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**Province**

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<https://ehmc.sbm.ac.ir>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Farnaz Sabrian  
**Position**  
Assistant Professor of Internal Medicine  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Fateme Talebian Taheri  
**Position**  
Student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
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fatimatalebian@ymail.com  
**Web page address**  
<https://ehmc.sbm.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 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. Fateme 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.sbm.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