Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the effect of carvedilol on cardiac function in patients with chronic myeloid leukemia treated with nilotinib and dasatinib in Sari city

Protocol summary

Study aim
Investigation of the effect of carvedilol on cardiac function in patients with chronic myeloid leukemia treated with nilotinib and dasatinib in Sari city

Design
The process of random allocation is provided by block method. This process will be done with Random Allocation Software. The ratio of allocation of samples between the two groups is 1:1. 30 samples.

Settings and conduct
oncology clinic at Imam Khomeini Hospital in Sari

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with CML treated with nilotinib and dasatinib for at least 1 y Age > 18 y Sinus rhythm of the heart Criteria for not entering the study: acute or chronic heart failure Low ejection fraction in echocardiography history of valvular heart disease or congenital heart disease; Systolic blood pressure <90 mm Hg or diastolic blood pressure <60 mm Hg. PR interval ≥ 240 ms second or third degree AV block History of asthma chronic obstructive pulmonary disease (COPD) and previous medical history of cardioprotective drugs (such as ACE inhibitors or dexrazoxane) Previous diagnosis of cardiomyopathy, history of CAD moderate to severe mitral and aortic disease, and AF consent to participate in the study

Intervention groups
Study subjects were divided into 2 control groups (patients with chronic myeloid leukemia treated with nilotinib and dasatinib who did not receive carvedilol) and intervention group (patients with chronic myeloid leukemia treated with nilotinib and dasatinib who received carvedilol)

Main outcome variables
LVEF level, Pro-BNP level Troponin level Change GLS Diameter of the left atrium Left ventricular systole and diastole diameter The thickness of the septum and the posterior wall of the left ventricle Initial mitral inflow velocity and delay The ratio of inflow velocity and mitral initial delay mitral inflow slowing time Pulmonary artery pressure QT Intertval

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241013063353N1**
Registration date: **2025-12-29, 1404/10/08**
Registration timing: **prospective**

Last update: **2025-12-29, 1404/10/08**
Update count: **0**

Registration date
2025-12-29, 1404/10/08

Registrant information

Name
ali bazram

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3434 3000

Email address
a.bazram@mazums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of carvedilol on cardiac function in patients with chronic myeloid leukemia treated with nilotinib and dasatinib in Sari city

Public title

Investigation of the effect of carvedilol on cardiac function in patients with chronic myeloid leukemia treated with nilotinib and dasatinib

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic myeloid leukemia treated with nilotinib and dasatinib for at least one year Age>18 Sinus rhythm of the heart

Exclusion criteria:

Acute and Chronic Heart Failure Low Ejection Fraction History of valvular heart disease or congenital heart disease Systolic blood pressure <90 mm Hg or diastolic blood pressure <60 mm Hg PR interval ≥ 240 ms AV block grade 2-3 History of Asthema Chronic Obsteractive Pulmonary Disease Previous medical history of cardioprotective drugs (such as ACE inhibitors or dexrazoxane) Previous diagnosis of cardiomyopathy, history of coronary artery disease, moderate to severe mitral and aortic disease, and atrial fibrillation. Lack of consent to participate in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The process of random allocation is provided by block method. This process will be done with Random Allocation Software. The ratio of allocation of samples between the two groups is 1:1. With the mentioned software, the number and size of blocks are determined by default to allocate 30 samples. The block size will be a multiple of 4 and 6. Samples that meet the inclusion criteria are included in the study based on randomly generated numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only the data analyst is blinded. And other people including the researcher, participants (patients included in the study) are aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran university of medical sciences

Street address

Vice chancellor for research and technology, Moalem Sq, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2025-01-23, 1403/11/04

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1403.114

Health conditions studied

1

Description of health condition studied

chronic myeloid leukemia

ICD-10 code

C92.1

ICD-10 code description

Chronic myeloid leukemia, BCR/ABL-positive

Primary outcomes

1

Description

Study of the effect of carvedilol on cardiac function in patients with chronic myeloid leukemia treated with nilotinib and dasatinib in Sari city.

Timepoint

Outcomes are measured at 0, 6, and 12 months.

Method of measurement

Based on echocardiography by an echocardiogram specialist and measurement of cardiac-specific biomarkers ProBNP, Troponin I

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Chronic myeloid leukemia patients treated with nilotinib and dasatinib undergoing carvedilol intervention
Category
Treatment - Drugs

2

Description
Control group: Chronic myeloid leukemia patients treated with nilotinib and dasatinib without intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Ramin Shekarriz
Street address
Cancer Lab, 3rd floor, Cancer comprehensive center, Imam Khomini hospital, Amir Mazandarani Blvd, Sari Town
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Sari
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Mazandaran
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r.shekarriz@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Jalal Ahmadi
Street address
Vice chancellor for research and technology, Moalem Sq, Sari, Iran
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Ali Bazram
Position
Internal Medicine specialist
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not 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 data can be shared
When the data will become available and for how long
After publishement
To whom data/document is available
Every one
Under which criteria data/document could be used
Without specific roules
From where data/document is obtainable
In addition to correspondence with the website of the magazine that publishes the project article, applicants can send their application to the executive or project manager if needed
What processes are involved for a request to access data/document
Searching the databases of article publishers online After sending the application to the project manager via email or fax number or visiting in person at the mentioned address and confirmed by the project manager, the information will be available to the applicants
Comments