

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

a pilot study to Assess the therapeutics indicators in Patients With Acute Myeloid Leukemia Undergoing therapy With deferasirox in Afzalipour Hospital of Kerman

Protocol summary

Study aim

Determining the clinical effect of deferasirox on the treatment of AML

Design

a clinical trial with a control group with parallel, double-blind, randomized control groups, phase 3, on 40 patients, a random number table is used for randomization.

Settings and conduct

This trial will be performed in the blood and oncology department of Afzalipour Hospital in Kerman. Patients whose type of disease and prognosis will be determined and also meet the conditions for inclusion in the study will be randomly admitted to one of the two intervention groups. The outcome assessor and the patients will be blind and patients will receive the desired intervention for 28 days. And then the primary and secondary variables will be evaluated on days 14 and 28 of the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 -65 years; both gender; patients with AML/non-APL. Exclusion criteria: HIV infected patients or Hepatitis B, C patients; patients with AML-induced neurological involvement; patients with uncontrolled blood pressure and heart failure; patients with a history of ocular toxicity due to iron chelators.

Intervention groups

Control group: standard treatment. Intervention group: standard treatment with deferasirox.

Main outcome variables

The rate of apoptotic cells of CD34 + leukemia blasts; the rate of Reactive oxygen species in CD34+ leukemia blast: the percentage of leukemia blasts in AML patients after receiving treatment.

General information

Reason for update

- Change of study site: due to relocation of the hematology and oncology ward from Shahid Bahonar Hospital in Kerman to Afzalipour Hospital -change the form of the intervention drug: based on the necessity of the prophylactic antifungal drugs administration to prevent side effects of the interventional drug and the difficulty of obtaining these drugs due to the coronavirus pandemic caused conditions, to reduce the potential hazards of intervention, the intravenous form of the drug (deferoxamine) is replaced by the oral form of that (deferasirox). The request for this change has been approved by the University Ethics Committee, recently. - time of starting the Patient recruitment: minimizing the potential risks of intervention for patients because of the weakened immune condition caused by the course of treatment in the coronavirus pandemic duration, a long-term process of negotiation with study sponsors to fund it due to provide the necessary laboratory materials and equipment to evaluate the outcomes of the study has not been possible up to now And it is estimated that would be possible in the next few months. -Randomization: Due to the importance of patients' prognosis and its effect on the expected therapeutic response rate, the method of randomization was changed from simple to permuted block randomization. -Blinding: To optimize the level of concealment, we changed the blindness from physician to data analyst

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20200313046756N2**
Registration date: **2021-05-08, 1400/02/18**
Registration timing: **prospective**

Last update: **2022-07-16, 1401/04/25**

Update count: **1**

Registration date

2021-05-08, 1400/02/18

Registrant information**Name**

Vahid Maazed

Name of organization / entity**Country**

Iran (Islamic Republic of)

Phone

+98 34 1223 5019

Email address

maazed@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

a pilot study to Assess the therapeutics indicators in Patients With Acute Myeloid Leukemia Undergoing therapy With deferasirox in Afzalipour Hospital of Kerman

Public title

Evaluation of the Effect of deferasirox on the treatment of Acute myeloid leukemia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-65 years AML/non-APL

Exclusion criteria:

HIV infected patients or Hepatitis B,C patients Patients with AML-induced neurological involvement Patients with uncontrolled blood pressure and heart failure Patients with a history of ocular toxicity due to iron chelators drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients divide into two groups $n = 20$ (including dropouts). Block permuted randomization method uses, based on that, patients organize in a three-level prognosis(A, B, C) in each three-person block of any interventional group. According to the random numbers chart, the researchers consider even numbers for the control group and odd numbers for the intervention group, then put their hand on one of the numbers and move upwards and record the numbers, and assign the patients based on that individual group

Blinding (investigator's opinion)

Double blinded

Blinding description

People will be kept blind. Patient: Receives the intervention drug in combination with the daily meals outcome assessor: The information of each patient is provided to the analyzer team in an unidentifiable manner with unique codes. They are also not aware of the details of the study process.

Placebo

Not used

Assignment

Parallel

Other design features

one group receiving standard treatment(without placebo) and the other group receive the standard treatment and interventional drug

Secondary Ids

empty

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

Research Ethics Committee of Kerman University of Medical Sciences

Street address

Beginning of Ibn Sina Street, First of Jihad Boulevard, Somayeh intersection (Tahmasb Abad)

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-11-23, 1399/09/03

Ethics committee reference number

IR.KMU.REC.1399.482

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

Acute myeloblastic leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description

The number of white blood cells

Timepoint

on days 14 and 28

Method of measurement

Test for complete blood cell count

2

Description

Number of red blood cells

Timepoint

on days 14 and 28

Method of measurement

Test for complete blood cell count

3

Description

platelet numbers

Timepoint

on days 14 and 28

Method of measurement

Test for complete blood cell count

4

Description

Percentage of CD34 + leukemia blasts of bone marrow biopsy specimen

Timepoint

on days 14 and 28

Method of measurement

Flow cytometry with CD34 monoclonal antibody

Secondary outcomes

1

Description

Reactive oxygen species rate in +CD34 leukemic blasts bone marrow biopsy sample

Timepoint

on days 14 and 28

Method of measurement

Flow cytometry

2

Description

The rate of apoptotic cells in +CD34 leukemic blasts bone marrow biopsy sample

Timepoint

on days 14 and 28

Method of measurement

Flow cytometry

Intervention groups

1

Description

Intervention group: receive the standard treatment Cytarabine and idarubicin (7+3) with oral intake of Deferasirox capsule 360 mg daily for 28 days

Category

Treatment - Drugs

2

Description

Control group: receive the standard treatment Cytarabine and idarubicin (7+3) without Placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital of Kerman

Full name of responsible person

Aliasghar Tirgar

Street address

Kerman Province, Kerman, Imam khomieni Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

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Fax

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Email

maazed@kmu.ac.ir

Web page address

<https://ah.kmu.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Kerman university of medical sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Kerman
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Phone
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Email
abpardakhty@kmu.ac.ir
Web page address
<http://kmu.ac.ir/fa>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

40

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

2

Sponsor

Name of organization / entity

Nano Fanavaran Alvand pharmaceutical co.

Full name of responsible person

Babak Yazdani

Street address

No. 485, Unit 52 Between 63 St & 65 St Yousef Abad
St. Tehran, IRAN

City

Tehran

Province

Tehran

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Fax

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Email

info@nanoalvand.com

Web page address

<http://www.nanoalvand.com>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nano Fanavaran Alvand pharmaceutical co.

Proportion provided by this source

30

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

3

Sponsor

Name of organization / entity

AryaTinaGene biopharmaceutical co.

Full name of responsible person

Behnam Taghavi

Street address

Second Sazandegi, Aq qalla Industrial state, Gorgan,
Iran

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Email

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Web page address

<http://www.atgbio.com/fa>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

AryaTinaGene biopharmaceutical co.

Proportion provided by this source

30

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Aliasghar Tirgar

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

no.14 , Alley 1 , shahidan ghotbi nezhad Ave,
Azadegan Blvd, Kerman Town

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Province

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Phone

0098342462413

Email

a.tirgar@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Vahid Moazed

Position

Associated Professor in Kerman University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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3 number Alley, Najafi Lary st., Jomhoori Islami Blvd,
Kerman, Iran

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Moazed_vahid@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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tirgar4@gmail.com

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 data will be initially de-identified. 1. Demographic Data of Participants: These data will generally be included in a table in the article. 2. Main outcome data: The article will be appended to the article in charts and tables as well as in an Excel file. Secondary outcome data in the article will be attached to the article in graphs and tables as well as in an Excel file.

When the data will become available and for how long

Starting data access period six months after the results are published

To whom data/document is available

Data will be available only to researchers working in academic and scientific institutions approved by the Ministry of Health

Under which criteria data/document could be used

The data will be available to researchers for further statistical analysis

From where data/document is obtainable

Refer to the person responsible for the project's scientific accountability to access the data

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

Applicants will submit a personal resume and the purpose of the data to the person responsible for the scientific account of the plan. The responsible person will be required to investigate the request within one week of sending the researcher information

Comments