Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Cardioeffects of deferoxamine in acute and delayed anthracyclins cardiotoxicities

Protocol summary

Summary

1- Objectives, to evaluate the efficacy of Deferoxamine in prevention of acute and delayed doxorubicin-induced cardio toxicity. 2- Design, the study is designed as a phase 3, open label, single center, and two arms clinical trial study. Sixty patients who eligible for inclusion criteria will be enrolled in the study. They will be divided into three groups with block randomization. 3- Setting and conduct, all stages of the project explain for each patient, and then if they want to enter the project inform consent would be obtained. The patients will be treated by different doses of Deferoxamine during chemotherapy. 4- Participants including major eligibility criteria, new pediatric cancer patients who are going to receive Anthracyclin drugs as part of their chemotherapy regimen. 5- Intervention, 10 to 20 mg/kg/day and 50 mg/kg/day dose regimen of Deferoxamine in two intervention groups, respectively. One group as control will receive no treatment. 6- Main outcome measures (variables), include assessing Troponin I, NT-proBNP, cardiac function with conventional and tissue doppler echocardiography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080615666N5**
Registration date: **2016-09-06, 1395/06/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-06, 1395/06/16

Registrant information

Name

Mohammad Reza Bordbar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cardioeffects of deferoxamine in acute and delayed anthracyclins cardiotoxicities

Public title

deferoxamine and its cardiotoxicity effects

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: signing informed consent; male or female aged between 2 to 18 years at screening; new pediatric cancer patients who are going to receive Anthracyclin drugs as part of their chemotherapy regimen Exclusion criteria: patients below two years old; patients with previous history of treatment with any kind

of chemotherapy or radiotherapy; diagnosis of congenital heart disease, preexisting heart failure and established renal disease

Age
From **2 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Ethics committee of Shiraz University of Medical Sciences

Street address
7th floor, Vice chancellery for research affairs, Shiraz University of Medical Sciences, Zand avenue, Shiaz, Iran

City
Shiraz

Postal code

Approval date
2016-03-12, 1394/12/22

Ethics committee reference number
ir.sums.med.rec.1394.83

Health conditions studied

1

Description of health condition studied
acute and chronic cardiopathy

ICD-10 code
I51.9

ICD-10 code description
Heart disease, unspecified

Primary outcomes

1

Description
cardiac Troponin-I

Timepoint
baseline, after the first dose of doxorubicin and after chemotherapy coarse

Method of measurement
hematology analysis

2

Description
NT-proBNP

Timepoint
baseline, after the first dose of doxorubicin and after chemotherapy coarse

Method of measurement
hematology analysis

3

Description
cardiac indexes

Timepoint
baseline, 3 and 12 months intervals

Method of measurement
Conventional and tissue doppler echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Deferoxamine 10 to 20 mg/kg. Frequency and route of administration is once per day continuous IV infusion over 8 hours.

Category
Treatment - Drugs

2

Description
Intervention group 2: Deferoxamine 50 mg/kg. Frequency and route of administration is once per day continuous IV infusion over 8 hours.

Category
Treatment - Drugs

3

Description
Control group: no treatment

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Nemazee hospital, Shiaz University of Medical Sciences, Shiraz, Iran
Full name of responsible person
Dr. Mohammad Reza Bordbar
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of research, Shiaz Univeisity of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
7th floor, Shiraz University of Medical Sciences, Zand avenue, Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of research, Shiaz Univeisity of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
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Mohammad Reza Bordbar
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Person responsible for updating data

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Position
general physician
Other areas of specialty/work
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Nemazee Hospital, Research Tower, Hematology Research Center
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty