

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of bolus infusion versus continuous injection of doxorubicin in children with ALL

Protocol summary

Study aim

Comparison of the cardiotoxic effects of continuous infusion and bolus injection of doxorubicin in children with ALL

Design

Clinical trial with two intervention groups with parallel groups, randomized, on 60 patients. A table of random numbers was used for randomization

Settings and conduct

Place of study: Shahid Sadoughi Hospital, Yazd. How to conduct the study: Patients are divided into two completely random groups according to the randomization table. The study is a single-blind study. The researcher does not know how to assign patients to two groups.

Participants/Inclusion and exclusion criteria

Entry conditions: normal echocardiography, written consent from parents, patients under 18 years of age, and patients with ALL who are using doxorubicin in their drug regimen. Exclusion criteria: previous history of chemotherapy or radiation therapy, diagnosis of congenital heart disease, heart failure, and kidney failure.

Intervention groups

Patients of both groups receive Adriamycin. Group A patients receive Adriamycin through bolus injection and Group B patients receive Adriamycin through continuous infusion.

Main outcome variables

Cardiotoxicity (EF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180209038673N7**

Registration date: **2024-01-02, 1402/10/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-02, 1402/10/12**

Update count: **0**

Registration date

2024-01-02, 1402/10/12

Registrant information

Name

Robab Sheikhpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3623 5958

Email address

r.sheikhpour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-20, 1402/09/29

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of bolus infusion versus continuous injection of doxorubicin in children with ALL

Public title

The effects of bolus infusion versus continuous injection of doxorubicin in children with ALL

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Normal echocardiography, Written consent from parents, patients under 18 years of age, patients with ALL who used doxorubicin in their drug regimen

Exclusion criteria:

Previous history of chemotherapy or radiation therapy
Diagnosis of congenital heart disease
Diagnosis of heart failure
Diagnosis of kidney failure

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of the two intervention groups is done based on quadruple blocks in Excel software. In this software, the intervention groups (A, and B) are placed alternately. In the next column, there are quadruple blocks. At the end, the random digits created by the software RND0 function are placed. We then arrange the numbers based on block columns and random values.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher does not know about prescription drugs. This means that the researcher knows the two groups only as group A and group B and has no knowledge of which intervention group the patients have been placed in. In other words, the researcher does not know which intervention groups A and B have received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical Schoole, Shahid Sadoughi University of Medical Sciences

Street address

Schoole of Medicine, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۶۰

Approval date

2023-06-26, 1402/04/05

Ethics committee reference number

IR.SSU.MEDICINE.REC.1402.126

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia

ICD-10 code

C91.00

ICD-10 code description

Acute lymphoblastic leukemia not having achieved remission

Primary outcomes

1

Description

cardiotoxicity effect

Timepoint

6 months after treatment

Method of measurement

Echocardiography

Secondary outcomes

1

Description

WBC measurement

Timepoint

6 months after therapy

Method of measurement

CBC instrument

Intervention groups

1

Description

Intervention group: Group A patients receive adriamycin through bolus injection. Before the intervention and 6 months after the intervention, the patients undergo echocardiography. The dose of Adriamycin is 40-60 mg/m² and it is purchased from Türkiye

Category

Treatment - Drugs

2

Description

Intervention group: Group B patients receive adriamycin through continuous infusion. Before the intervention and

6 months after the intervention, the patients undergo echocardiography. The dose of Adriamycin is 40-60 mg/m² and it is purchased from Türkiye

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of blood and Oncology, Shahid Sadoughi hospital

Full name of responsible person

Dr Elnaz Sheikhpour

Street address

Shhid Sadoughi hospital, Ebn Sin Blvd, Safaei, Yazd

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r.sheikhpour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Amin Salehi

Street address

Research Assistant, Imam Reza Building, Imam Hossein Square, Yazd,

City

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Phone

+98 35 3628 9180

Email

Research@offices.yazd.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr Elnaz Sheikhpour

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available