

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation the efficacy of oral coenzyme Q10 supplement on protection of Anthracycline-induced cardiotoxicity in pediatric malignancies

Protocol summary

Summary

Main goal: evaluation the efficacy of oral coenzyme Q10 supplement on protection of Anthracycline-induced cardiotoxicity in pediatric malignancies. Study design: randomized clinical trial, double blind with placebo. Inclusion criteria: age between 1 and 16 years old; normal kidney and liver function; malignancy and under treatment with anthracyclines; LVEF deterioration between 30 and 40%. Exclusion criteria: food supplement or other dietary regimen; congenital heart disease; other systemic disease other than cancer. Patients suffering from cancer who referred to Shafa Hospital under supervision of oncologist and are under treatment with Anthracyclines will be recruited in this study. Sample size in each group will be 10. All of them after LVEF reduction divide in two groups and then under the supervision of dietitian will take Coenzyme Q10 at 20 mg for about 3 months. After that electrocardiogram and echocardiography will take again for analyzing and comparison following parameters between case and control before and after trial. Left ventricular volume chamber; left ventricular end diastolic diameter; left ventricular end systolic diameter; left ventricular ejection fraction; left ventricular fraction shortening; electrocardiogram parameters including QRS voltage; QT interval; QRS interval; PQ interval; deep S wave; deep Q wave, tall R wave and cardiac rate will be evaluated and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101026390N3**
Registration date: **2016-10-23, 1395/08/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-23, 1395/08/02

Registrant information

Name

Ehsan Ghaedi

Name of organization / entity

Ahwaz Jundishapoor ,University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3285

Email address

ghaedi.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapour University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of oral coenzyme Q10 supplement on protection of Anthracycline-induced cardiotoxicity in pediatric malignancies

Public title

The Effect Coenzyme Q10 on cardiac complacation after chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 1 and 16 years old; normal kidney and liver function; malignancy and under treatment with antracyclines; LVEF deterioration between 30 and 40%. Exclusion criteria: food supplement or other dietary regimen; congenital heart disease; other systemic disease other than cancer.

Age

From **1 year** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz Jundishapour University of Medical Sciences

Street address

Ahwaz Jundishapour University of Medical Sciences,
Shahre Daneshgahi

City

Ahwaz

Postal code

Approval date

2016-06-18, 1395/03/29

Ethics committee reference number

IR.AJUMS.REC.1395.197

Health conditions studied

1

Description of health condition studied

Lymphoblastic Leukemia

ICD-10 code

C91

ICD-10 code description

Lymphoid leukaemia

2

Description of health condition studied

Hodgkin Lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

Primary outcomes

1

Description

Left Ventricular Chamber Volume

Timepoint

Before and after intervention

Method of measurement

Echocardiography

2

Description

Left Ventricular End Diastolic Diameter

Timepoint

Before and after intervention

Method of measurement

Echocardiography

3

Description

Left Ventricular End Systolic Diameter

Timepoint

Before and after intervention

Method of measurement

Echocardiography

4

Description

Left Ventricular Ejection Fraction

Timepoint

Before and after intervention

Method of measurement

Echocardiography

5

Description

Left Ventricular Fraction Shortening

Timepoint

Before and after intervention

Method of measurement

Echocardiography

6

Description

Electrocardiogram interpretation

Timepoint

Before and after intervention

Method of measurement

Electrocardiogram

Secondary outcomes

1

Description

Weight

Timepoint

Before and after intervention

Method of measurement

Sensitive Scale

Intervention groups

1

Description

Patients Under supervision of Nutritionist, Oncologist and cardiologist for taking Coenzyme Q10 200 mg for 3 monthes will select.

Category

Treatment - Drugs

2

Description

Patients in control group will recieve placebo in the same number of intervention group for three monthes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Kaveh Jaseb Oncologist

Street address

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

Full name of responsible person

Sharif Makhmalzede

Street address

Ahwaz Jundishapour University of Medical Sciences,
Shahre Daneshgahi

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahwaz Jundishapour University 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

Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person

Kaveh Jaseb

Position

Pediatric Oncologist

Other areas of specialty/work

Street address

Shafa Hospital, Ahwaz

City

Ahwaz

Postal code

Phone

+98 61 3374 3285

Fax

Email

k_jaseb@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hemoglobinopathy Center

Full name of responsible person

Ehsan Ghaedi

Position

Nutritionist

Other areas of specialty/work

Street address

Hemoglobinopathy Center, University of Medical
Science, Ahwaz

City

Ahwaz

Postal code

Phone

+98 61 3374 3285

Fax

Email

en7cyrus@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Haemoglobinopathy Center

Full name of responsible person

Ehsan Ghaedi

Position

Nutritionist

Other areas of specialty/work**Street address**

Haemoglobinopathy Center, Shafa Hospital

City

Ahwaz

Postal code**Phone**

+98 61 3374 3285

Fax**Email**

Web page address

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