

# 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 Jundishapoor 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

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en7cyrus@gmail.com

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## 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*