

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Evaluation the efficacy of Coenzyme Q10 on Bortozomib and Thalidomide induced Neurotoxicity(Neuropathy) in patient with Multiple Myeloma malignancy

Protocol summary

Summary

Main goal: evaluation the efficacy of Coenzyme Q10 on Bortozomib and Thalidomide induced Neurotoxicity (Neuropathy) in patient with Multiple Myeloma malignancy. Inclusion criteria: age between 30 and 70 years old; normal function for liver and kidney; multiple myeloma diagnosed patients. Exclusion criteria: chemotherapy; neuropathy due to diabetes, HIV, alcohol abuse, thyroid dysfunction; congenital neurological dysfunction; dietary supplement 2 months before the study. Patients with Multiple Myeloma who referred to Shafa hospital, Ahwaz, Iran under supervision of oncologist will be recruited in this study. Sample size in each group will be 30. All of them before chemotherapy are divided in two groups. Randomization is applied by nurse with simple randomized number and researcher, physician and patient not familiar with allocation. Then under the supervision of dietitian will be under supplementation with 200 mg Coenzyme Q10. Then electromyography applies for analyzing following parameters: a-SAP, sensory action potential amplitude; SCV, sensory conduction velocity, DML, distal motor latency; a-CMAP, amplitude of compound muscle action potential; MCV, motor conduction velocity. Also validated questionnaire will be completed. All the Neurological parameters will be performed under supervision of Neurologist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110626390N6**
Registration date: **2016-11-22, 1395/09/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-22, 1395/09/02

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

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapour University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of Coenzyme Q10 on Bortozomib and Thalidomide induced Neurotoxicity(Neuropathy) in patient with Multiple Myeloma malignancy

Public title

Evaluation the efficacy of q10 on Neurological Complication in Multiple Myeloma

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 30 and 70 years old; normal function for liver and kidney; multiple myeloma diagnosed patients. Exclusion criteria: chemotherapy; neuropathy due to diabetes, HIV, alcohol abuse, thyroid dysfunction; congenital neurological dysfunction; dietary supplement 2 months before the study.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

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,
University town, Ahwaz

City

Ahwaz

Postal code**Approval date**

2015-10-17, 1394/07/25

Ethics committee reference number

IR.AJUMS.REC.1394.394

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

Multiple myeloma

ICD-10 code

C90.0

ICD-10 code description

Multiple myeloma

Primary outcomes**1****Description**

a-SAP, sensory action potential amplitude

Timepoint

before intervention and 3 months after that

Method of measurement

Electromyography

2**Description**

SCV, sensory conduction velocity

Timepoint

before intervention and 3 months after that

Method of measurement

Electromyography

3**Description**

DML, distal motor latency

Timepoint

before intervention and 3 months after that

Method of measurement

Electromyography

4**Description**

a-CMAP, amplitude of compound muscle action potential

Timepoint

before intervention and 3 months after that

Method of measurement

Electromyography

5**Description**

MCV, motor conduction velocity

Timepoint

before intervention and 3 months after that

Method of measurement

Electromyography

Secondary outcomes**1****Description**

Weight

Timepoint

Before intervention and 3 months after that

Method of measurement

Sensitive Balance

Intervention groups

1

Description

Patients in intervention group will receive Q10 at dose of 200 milligram daily for 3 months. Q10 purchase from Livaar Company in 100 mg and patient will receive 2 times a day

Category

Treatment - Other

2

Description

Patients in control group will receive 2 times a day of wheat flour for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Dr. Ahmadzade, Oncologist

Street address

Shafa Hospital, Farvardin Street, Golestan Bolvard, Ahwaz

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of research Ahwaz Jundishapour University of Medical Sciences

Full name of responsible person

Sharif Makhmalzadeh

Street address

Grand Flour, Vice president of Research Department, Ahwaz Jundishapour University of Medical Sciences, University Town, Ahwaz

City

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice President of research 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 Jundishapour University of Medical Science

Full name of responsible person

Ahmad Ahmadzadeh

Position

Oncologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Nutritionist

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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