Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 efficay 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 recieve Q10 at dose of 200 millgram dialy for 3 months. Q10 purchase from Livaar Company in 100 mg and patient will recieve 2 times a day
Category
Treatment - Other

2

Description
Patients in control group will recieve 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
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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
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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