Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The protective effect of Thiamine (vitamin B1) for Bortezomib induced peripheral neuropathy in multiple myeloma

Protocol summary

Study aim
We aimed to evaluate the role of vitamin B1 (Thiamine) on prevention of Bortezomibe induced peripheral neuropathy (BIPN) in patients with multiple myeloma in this study

Design
This was a randomized controlled clinical trial study

Settings and conduct
Patients with multiple myeloma who were supposed to receive 4 months of Bortezomib based chemotherapy enrolled in this study. The patient's were divided into two groups. Intervention group received Thiamine at a dose of 300 mg per day from the beginning of treatment schedules and the control group received only the standard regimen of bortezomibe chemotherapy. A symptom-based questionnaire was used to evaluate these patients. Isfahan

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men and women with MM in Isfahan city who were suspected to receive Bortezomib based chemotherapy regimen and did not have interfering factors such as: Previous history of symptomatic peripheral neuropathy, Diabetes mellitus, End stage renal disease, history of alcohol abuse, and any other neuromuscular disease.

Intervention groups
Intervention group: Patients who treated with bortezomibe with a dose of 1.3 mg per m2 and vitamin B1 simultaneously. (Vitamin B1 at a dose of 300 mg per day orally) Control group: Patients who treated with bortezomibe with a dose of 1.3 mg per m2 for body alone, and no other drugs have been used to prevent the onset of neuropathy.

Main outcome variables
neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190116042379N1**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**

Registration date
2019-02-14, 1397/11/25

Registrant information

Name
ghazal rafiaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3261 3680

Email address
ghazalrafiaei@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-16, 1397/10/26

Expected recruitment end date
2019-03-17, 1397/12/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The protective effect of Thiamine (vitamin B1) for Bortezomib induced peripheral neuropathy in multiple

myeloma

Public title
The protective effect of Thiamine (vitamin B1) for Bortezomib induced peripheral neuropathy in multiple myeloma
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
who were suspected to receive Bortezomib based chemotherapy regimen
Exclusion criteria:
do not have interfering factors such as: Previous history of symptomatic peripheral neuropathy, Diabetes mellitus, End stage renal disease, history of alcohol abuse, and any other neuromuscular disease
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a number was assigned to each patient and dividing into two intervention and control groups was done using random numbers table.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University
City
Isfahan
Province
Isfehan
Postal code
8158136884
Approval date
2017-05-31, 1396/03/10
Ethics committee reference number
IR.mui.rec.1396.3.051

Health conditions studied

1

Description of health condition studied
neuropathy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
neuropathy
Timepoint
4month
Method of measurement
experimental symptom-based questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients treated with bortezomibe with a dose of 1.3 mg per m2 and vitamin B1 simultaneously. (Vitamin B1 at a dose of 300 mg per day orally).
Category
Prevention

2

Description
Control group: Patients treated with bortezomibe with a dose of 1.3 mg per m2 for body alone, and no other drugs have been used to prevent the onset of neuropathy.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid(Seiedolshohada) hospital
Full name of responsible person
Ghazal Rafiaei
Street address
Seiedolshohada Hospital. Motahari Ave

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person

Street address
Isfahan University
City
Isfahan
Province
Isfehan
Postal code
5555555555
Phone
+98 31 3333 3333
Email
ghazalrafiaei@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan university
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
Esfahan University of Medical Sciences
Full name of responsible person
Ghazal Rafiaei
Position
doctor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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No4. Arshida Beilding. Shadiha Alley. Bazarcheh Ave.2th Moshtagh street
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable