

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Bortezomib 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 bortezomib 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 bortezomib 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 bortezomib 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

Isfahan

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
Isfahan
Postal code
5555555555
Phone
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Email
ghazalrafaei@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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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