Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evalute and compare the effectiveness of oral thalidomide + Bortezomib (subcutaneous) + Dexamethasone(IV) regimen with Bortezomib (subcutaneous) + oral prednisolone + oral thalidomide regimen in patients with newly diagnosed multiple myeloma

Protocol summary

Summary

In this study to evaluate and compare the therapeutic effect Bortezomib subcutaneous + Dexamethasone (IV) + thalidomide oral with Bortezomib subcutaneous + oral prednisolone + thalidomide orally in patients with newly diagnosed multiple myeloma. In this study, which is done as a simple randomized clinical trial, 30 patients with newly diagnosed multiple myeloma who wish to participate in the study, and written informed consent form to complete, beginning with clinical trials including CBC-BUN-Cr-ESR-CRP-Ca-Alb-B2M-LDH-Electrophoresis of serum Pr and urine & BMA/B Divided into 2 groups: 1: 3 cycles of Bortezomib S.C (1.3 mg/m2 on days 1, 4, 8, and 11 at 3-week intervals Dexamethasone (40 mg I.V on days 1, 4, 8, and 11 at 3-week intervals) Tab Thalidomide (100 mg P.O Daily D1_D21) 2: 3 cycles of Bortezomib S.C (1.3 mg/m2 on days 1, 4, 8, and 11 at 3-week intervals) Tab Prednisolone (100 mg P.O on days 1_ 4, and 8_11 at 3-week intervals) Tab Thalidomide (100 mg P.O Daily D1_ D21) After 4 cycles of treatment to assess response to treatment clinical trials and once again BMA / B and flow cytometry repeated. In addition, the side effects of therapy in the two study groups was determined and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032633143N1**
Registration date: **2017-09-17, 1396/06/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-17, 1396/06/26

Registrant information

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Mohmadamir Sarabi
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Pay personal expenses

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2018-03-18, 1396/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evalute and compare the effectiveness of oral thalidomide + Bortezomib (subcutaneous) + Dexamethasone(IV) regimen with Bortezomib (subcutaneous) + oral prednisolone + oral thalidomide regimen in patients with newly diagnosed multiple myeloma

Public title
Effectiveness of prednisolone in treatment of multiple myeloma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Newly diagnosed patients with multiple myeloma who have over 18 years of age and are willing to participate in this study. Exclusion criteria: HIV-positive patients, patients with a history of malignant, uncontrolled diabetes, neuropathy grade 2 diabetes, significant liver and kidney and heart failure are excluded.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Tehran University of Medical Sciences
Street address
Poursina St, North Side of Tehran University, School of Medicine
City
Tehran
Postal code
1417613151
Approval date
2017-03-14, 1395/12/24
Ethics committee reference number
IR.TUMS.IKHC.REC.1395.1972

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
Effectiveness
Timepoint
After 4 courses of treatment
Method of measurement
Check list and interviews

2

Description
side effects
Timepoint
After 4 courses of treatment
Method of measurement
Check list and interviews

Secondary outcomes

1

Description
Plt changes
Timepoint
After 4 courses of treatment
Method of measurement
check list and interviews

2

Description
Neuropathy
Timepoint
After 4 courses of treatment
Method of measurement
check list and interviews

3

Description
The cost of treatment
Timepoint
After 4 courses of treatment
Method of measurement
check list and interviews

4

Description
WBC changes
Timepoint

After 4 courses of treatment

Method of measurement

check list and interviews

5

Description

The number of pack cell

Timepoint

After 4 courses of treatment

Method of measurement

check list and interviews

6

Description

Quality of Life

Timepoint

After 4 courses of treatment

Method of measurement

check list and interviews

Intervention groups

1

Description

Inervention group Tab prednisolone 100 mg on day 1 to 4th and day 8 to eleventh in the form of orally administered for 4 (21-day) cycles

Category

Treatment - Drugs

2

Description

Control group by intravenous dexamethasone 40 mg on days 1, 4, 8 and 11 administered for 4 (21-day) cycles

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Mohamadamir Sarabi

Street address

Bagherkhan Street, Tohid Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Personal

Full name of responsible person

Mohamadamir Sarabi

Street address

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Personal

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

Tehran University of Medical Sciences

Full name of responsible person

Mohamadamir Sarabi

Position

Resident of Hematology & Oncology

Other areas of specialty/work

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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