

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name

Mohmadamir Sarabi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 1382

Email address

msarabi@razi.tums.ac.ir

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
Intervention 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
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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