

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

**A phase III, randomized, parallel, two-arm, double-blind, multi-center, active-controlled, non-inferiority clinical trial to compare efficacy and safety of daratumumab (produced by CinnaGen Co.) versus the reference daratumumab (Darzalex®, produced by Janssen Biotech, Inc.) in relapsed or refractory multiple myeloma patients**

### Protocol summary

#### Study aim

To assess the non-inferiority, efficacy, safety, and immunogenicity of daratumumab (manufactured by CinnaGen Co.) in comparison with Darzalex® (manufactured by Janssen Biotech, Inc.) in relapsed or refractory multiple myeloma patients

#### Design

A phase III, randomized, parallel, two-arm (with 1:1 ratio), double-blind (patients and evaluators), multi-center, active-controlled, non-inferiority clinical trial

#### Settings and conduct

Patients with relapsed or refractory multiple myeloma will be randomly assigned to the groups. Then, over the course of 24 visits (52 weeks), the therapeutic intervention (DRd regimen) will be administered in both groups according to the study protocol. Laboratory assessments and, if necessary, imaging studies will also be performed at each scheduled visit in accordance with the protocol.

#### Participants/Inclusion and exclusion criteria

Eligible patients are adults  $\geq 18$  years with informed consent, a confirmed diagnosis of multiple myeloma per IMWG criteria, one or two prior lines of therapy, prior response (Partial Response or better), and progressive disease. Exclusion applies to prior anti-CD38 therapy, refractoriness to lenalidomide, or other concurrent conditions that may compromise safety or study integrity.

#### Intervention groups

Intervention group: Daratumumab (manufactured by CinnaGen Co.); Control group: Darzalex®. Both arms receive DRd regimen for 14 28-day cycles. This regimen consists of daratumumab 16 mg/kg intravenous infusion once weekly (cycles 1-2), every two weeks (cycles 3-6),

and every four weeks (cycles 7 and beyond); lenalidomide 25 mg orally once daily, on days 1-21 of each 28-day cycle; and dexamethasone 40 mg orally once weekly.

#### Main outcome variables

The proportion of subjects who achieve Very Good Partial Response (VGPR) or better per International Myeloma Working Group criteria, within one year after treatment initiation

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20150303021315N38**  
Registration date: **2025-10-28, 1404/08/06**  
Registration timing: **prospective**

Last update: **2025-10-28, 1404/08/06**

Update count: **0**

#### Registration date

2025-10-28, 1404/08/06

#### Registrant information

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**Recruitment status**

recruiting

**Funding source****Expected recruitment start date**

2025-11-22, 1404/09/01

**Expected recruitment end date**

2026-11-23, 1405/09/02

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A phase III, randomized, parallel, two-arm, double-blind, multi-center, active-controlled, non-inferiority clinical trial to compare efficacy and safety of daratumumab (produced by CinnaGen Co.) versus the reference daratumumab (Darzalex®, produced by Janssen Biotech, Inc.) in relapsed or refractory multiple myeloma patients

**Public title**

A comparison of the efficacy and safety of daratumumab (produced by CinnaGen Co.) versus the reference daratumumab (Darzalex®, produced by Janssen Biotech, Inc.) in relapsed or refractory multiple myeloma patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of at least 18 years old at the time of randomization  
Willingness for signing and having signed the written informed consent form  
Diagnosis of multiple myeloma per IMWG criteria:  
3.1. Clonal bone marrow plasma cells  $\geq 10\%$  at some point in their disease history or presence of a biopsy-proven plasmacytoma  
3.2. Measurable disease as defined by any of the following:  
3.2.1. IgG multiple myeloma: Serum monoclonal paraprotein (M-protein) level  $\geq 1.0$  g/dL or urine M-protein level  $\geq 200$  mg/24h  
3.2.2. IgA, IgM, IgD, or IgE multiple myeloma: serum M-protein level  $\geq 0.5$  g/dL or urine M-protein level  $\geq 200$  mg/24h  
Subject must have received at least one prior line of therapy for multiple myeloma. A line of therapy consists of 1 complete cycle of a single agent, a regimen consisting of a combination of several drugs, or a planned sequential therapy of various regimens (eg, 3-6 cycles of initial therapy with bortezomib-dexamethasone followed by stem cell transplantation, consolidation, and lenalidomide maintenance is considered 1 line). Subject must have achieved a response (Partial Response or Better based on investigator's determination) to at least one prior regimen. Subject must have progressive disease, based on investigator's determination, on or after their last regimen  
Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2

**Exclusion criteria:**

Subject has received daratumumab or other anti-CD38 therapies previously. Subject's disease shows evidence of refractoriness to any dose of lenalidomide, defined either:  
2.1. Subjects whose disease progresses within 60

days of the last dose of lenalidomide; or  
2.2. Subjects whose disease is nonresponsive while on lenalidomide. Nonresponsive disease is defined as either failure to achieve at least a Minimal Response or development of PD while on lenalidomide. Subject has received anti-myeloma treatment within 2 weeks before the date of randomization. The only exception is emergency use of a short course of corticosteroids (equivalent of dexamethasone 40 mg/day for a maximum 4 days) before treatment. Subject has received more than two prior lines of therapy for multiple myeloma. Subject has received autologous stem cell transplant within 12 weeks before the date of randomization, or subject has previously received an allogeneic stem cell transplant (regardless of timing) Subject in need of stem cell transplant during the study period (in investigator's opinion), or planning to undergo a stem cell transplant prior to disease progression in this study, ie, these subjects should not be enrolled in order to reduce disease burden prior to transplant. A history of malignancy (other than multiple myeloma) within 5 years before the date of randomization, with the exception of squamous and basal cell carcinomas of the skin, carcinoma in situ of the cervix, or a malignancy that in the opinion of the investigator is considered cured with minimal risk of recurrence within 5 years  
Subject has known meningeal involvement of multiple myeloma  
Known chronic obstructive pulmonary disease (COPD) of grade GOLD 3 (severe) or GOLD 4 (very severe) based on Global Initiative for Chronic Obstructive Lung Disease (GOLD)  
Current uncontrolled persistent asthma in time of screening (per American Lung Association's classification)  
Human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) seropositivity; This criterion is assessed via HBs-Ag, HBc-Ab, HCV-Ab, and HIV-Ab tests at screening. Subject has any of the following laboratory test results during the Screening Phase:  
12.1. Aspartate aminotransferase (AST) or alanine aminotransferase level (ALT)  $\geq 2.5$  times the upper limit of normal (ULN)  
12.2. Alkaline phosphatase level  $\geq 2.5 \times$  ULN  
12.3. Total bilirubin level  $\geq 1.5 \times$  ULN, (except for Gilbert Syndrome: direct bilirubin  $1.5 \times$  ULN)  
Subject has known hypersensitivity to monoclonal antibodies or human proteins  
Subject has plasma cell leukemia ( $> 2.0 \times 10^9/L$  circulating plasma cells by standard differential), Waldenström's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), monoclonal gammopathy of undetermined significance (MGUS), smoldering myeloma, or amyloidosis  
Pregnant or nursing women, or female/male subject planning to become pregnant while enrolled in this study, within 4 weeks after the last dose of lenalidomide, or within 12 weeks after the last dose of daratumumab. Female and male subjects in the reproductive age must use reliable methods of contraception. Subject has received an investigational drug within 4 weeks before randomization (except for investigational anti-myeloma agents, which cannot be taken within 2 weeks prior to randomization, as described in exclusion criterion #3)  
Subject has had major surgery within 2 weeks before randomization, or

will not have fully recovered from surgery, or has surgery planned during the time the subject is expected to participate in the study or within 2 weeks after the last dose of study treatment. Note: subjects with planned surgical procedures to be conducted under local anesthesia may participate. Kyphoplasty or vertebroplasty are not considered major surgery. Has had a plasmapheresis within 28 days before randomization Radiation therapy (with the exception of palliative radiation therapy) within 14 days before randomization Subject has any concurrent medical condition or disease (eg, active systemic infection) that is likely to interfere with study procedures or results, or that in the opinion of the investigator would constitute a hazard for participating in this study

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **128**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization of patients will be conducted using Stata software (v. MP 18, StataCorp, US.), utilizing block randomization (with size 2 and 4) stratified by disease stage (I, II or III) and number of prior lines of therapy (1 or 2) for a total of 128 patients (with a 1:1 ratio). Prior to the start of the study, the generated randomization series, along with the seed used for generating random numbers. The randomization process will be performed centrally, meaning that each patient will be allocated to one of these strata upon entering the study based on their conditions. Then, by contacting the unit responsible for randomization, they will be assigned to a treatment group using the random list corresponding to that stratum. Each randomized patient will be assigned a unique identification code for the duration of the study. The assigned code will consist of four letters (the first two letters of the first name and the first two letters of the last name), three numbers (the center code), three letters representing the generic drug name (which is DRT), and three digits (corresponding to the randomization code), forming the patient code. For example: ABCD001 DRT-001. The randomization numbers will be assigned sequentially.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both vials of daratumumab (manufactured by SinaGen Research and Production Company) and Darzalex®

(manufactured by Janssen Biotech, Inc.) used in the study were indistinguishable to patients and study staff, as they were completely identical in shape, size, material, and color, and therefore the brand of the drug could not be identified by appearance. The drug containers of daratumumab (manufactured by SinaGen Research and Production Company) and Darzalex® (manufactured by Janssen Biotech, Inc.) were also placed in identical packaging, making them visually indistinguishable. Randomization will not be disclosed to the study investigators. Individuals responsible for data review and analysis will remain blinded to patient group allocation.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Dr. Shariati Educational, Research and Clinical Center  
Ethics Committee, TUMS

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**Province**

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**Postal code**

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**Approval date**

2025-10-01, 1404/07/09

**Ethics committee reference number**

IR.TUMS.SHARIATI.REC.1404.077

**Health conditions studied****1****Description of health condition studied**

Relapsed or Refractory Multiple Myeloma

**ICD-10 code**

C90.0

**ICD-10 code description**

Multiple myeloma

**Primary outcomes****1****Description**

The proportion of subjects who achieve Very Good Partial Response (VGPR) or better per IMWG criteria, within one year after treatment initiation

**Timepoint**

From randomization up to 12 months

**Method of measurement**

Response, based on International Myeloma Working Group (IMWG) criteria

## Secondary outcomes

### 1

**Description**

Duration of Response (DOR): The duration from the first documented VGPR or better per IMWG criteria, to the date of first documented progressive disease per IMWG criteria

**Timepoint**

From randomization up to 12 months

**Method of measurement**

Response, based on International Myeloma Working Group (IMWG) criteria

### 2

**Description**

Overall Survival (OS): Time from the randomization date to the date of the subject's death due to any cause

**Timepoint**

From randomization up to 12 months

**Method of measurement**

Recording of the duration from the date of randomization to the date of the subject's death due to any cause

### 3

**Description**

Overall Response Rate (ORR): The proportion of subjects who achieve Partial Response (PR) or better per IMWG criteria, within one year after treatment initiation

**Timepoint**

From randomization up to 12 months

**Method of measurement**

Response, based on International Myeloma Working Group (IMWG) criteria

### 4

**Description**

Time to Response (TTR): Time from the randomization date to VGPR or better per IMWG criteria

**Timepoint**

From randomization up to 12 months

**Method of measurement**

Response, based on International Myeloma Working Group (IMWG) criteria

### 5

**Description**

Time to progression (TTP): Time from the randomization date to progressive disease per IMWG criteria

**Timepoint**

From randomization up to 12 months

**Method of measurement**

Response, based on International Myeloma Working Group (IMWG) criteria

### 6

**Description**

Progression-Free Survival (PFS): The duration from the date of randomization to either progressive disease per IMWG criteria, or death, whichever occurs first

**Timepoint**

From randomization up to 12 months

**Method of measurement**

Response, based on International Myeloma Working Group (IMWG) criteria

### 7

**Description**

Evaluation of incidence of daratumumab adverse events

**Timepoint**

During all visits including screening visit; up to one month after the last injection; before, during, and after each intervention (until the next intervention is received)

**Method of measurement**

Assessment of the adverse events reported by the patient or physician, and evaluation of severity, seriousness and causal relationship of adverse events with daratumumab based on international guidelines, such as the guidelines of the World Health Organization

### 8

**Description**

Assessment of anti-daratumumab antibody development in patients.

**Timepoint**

At screening visit and weeks 24 and 52 after initiation of treatment with daratumumab

**Method of measurement**

Blood sampling for the evaluation of anti-daratumumab antibody serum using ELISA method

## Intervention groups

### 1

**Description**

Intervention group:- Daratumumab (manufactured by CinnaGen Co.) 16 mg/Kg intravenous infusion once weekly (cycles 1-2), every two weeks (cycles 3-6), and every four weeks (cycles 7 and beyond) - Lenalidomide 25 mg orally once daily, on days 1-21 of each 28-day cycle- Dexamethasone 40 mg orally once weekly

**Category**

Treatment - Drugs

### 2

**Description**

Control group:- Daratumumab (Darzalex®),

manufactured by Janssen Biotech, Inc.) 16 mg/kg intravenous infusion once weekly (cycles 1-2), every two weeks (cycles 3-6), and every four weeks (cycles 7 and beyond) - Lenalidomide 25 mg orally once daily, on days 1-21 of each 28-day cycle- Dexamethasone 40 mg orally once weekly

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Taleghani Hospital

###### Full name of responsible person

Dr. Sayeh Parkhideh/ Dr. Sahar Parkhideh/ Dr. Mojtaba Ghadiany/ Dr. Mahshid Mehdizadeh

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#### 2

##### Recruitment center

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Dr. Sahar Tavakkoli Shiraji/ Dr. Mohammad Vaezi/ Dr. Soroush Rad/ Dr. Maryam Barkhordar

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##### Recruitment center

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#### 4

##### Recruitment center

###### Name of recruitment center

Naft Hospital

###### Full name of responsible person

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##### Recruitment center

###### Name of recruitment center

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**8****Recruitment center****Name of recruitment center**

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**9****Recruitment center****Name of recruitment center**

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**10****Recruitment center****Name of recruitment center**

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**11****Recruitment center****Name of recruitment center**

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**12**

**Recruitment center**

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Shahid Ghazi Hospital

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Nejati

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

CinnaGen Company

**Full name of responsible person**

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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**

CinnaGen Company

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Industry

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Orchid Pharmed Co.

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Medical Department Manager

**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable