

The MM5 trial: evaluation of two regimens of bortezomib-based induction therapy and of lenalidomide consolidation followed by lenalidomide maintenance treatment in patients with multiple myeloma

Submission date 16/04/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 27/04/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/11/2025	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MM5

Study information

Scientific Title

Randomised phase III trial for previously untreated multiple myeloma to evaluate two regimens of bortezomib based induction therapy and lenalidomide consolidation followed by lenalidomide maintenance treatment

Acronym

MM5

Study objectives

The MM5 trial is designed to address two independent primary objectives. The primary objectives of the study are:

1. Demonstration of non-inferiority of VCD (bortezomib, cyclophosphamide, dexamethasone) induction therapy compared to PAd (bortezomib, adriamycin, dexamethasone) induction therapy with respect to response rate (very good partial remission or better; response criteria of the International Myeloma Working Group [IMWG])
2. Determination of the best of four treatment strategies with respect to progression-free survival (PFS). The four treatment strategies are defined by PAd versus VCD induction treatment, standard intensification therapy, lenalidomide consolidation and maintenance treatment with lenalidomide for 2 years versus lenalidomide until complete response (CR).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethikkommission der Medizinischen Fakultät Heidelberg, University of Heidelberg, pending as of 16/04/2010

Primary study design

Interventional

Study design

Prospective multicentre multinational randomised parallel group open phase III clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple myeloma

Interventions

Patients are randomised into four treatment arms (A1, A2, B1, B2).

Patients included in arms A1/B1 are treated with 3 cycles PAd (bortezomib 1.3 mg/m² intravenous [iv] on days 1, 4, 8 and 11, doxorubicin 9 mg/m² iv on days 1 - 4, dexamethasone [Dex] orally [po] 20 mg/d on days 1 - 4, 9 - 12 and 17 - 20).

Patients in arm A2/B2 are treated with 3 cycles VCD (bortezomib 1.3 mg/m² iv on days 1, 4, 8 and 11, cyclophosphamide 900 mg/m² iv on day 1, dexamethasone po 40 mg/d on days 1 - 2, 4 - 5, 8 - 9, 11 - 12).

Standard intensification treatment will be done according to local protocols.

Thereafter, two cycles of lenalidomide 25 mg/d on days 1 - 21 are given, followed by a lenalidomide maintenance treatment (lenalidomide orally [po] 10 mg/d in the first three months, thereafter 15 mg/d). In arms A1 and A2 lenalidomide maintenance will be given for a period of 2 years, in arms B1 and B2 until a CR is reached.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

VCD (bortezomib, cyclophosphamide, dexamethasone), PAd (bortezomib, adriamycin, dexamethasone)

Primary outcome(s)

1. Response to treatment (very good partial remission or better) after induction therapy, measured after induction therapy
2. Progression-free survival (i.e., time from randomisation to progression or death from any cause whichever occurs first), measured at several timepoints during study and follow up if there is a progression of the disease

Key secondary outcome(s)

1. Overall survival defined as time from randomisation to death from any cause. Patients still alive or lost to follow up are censored at the date they were last known to be alive.
2. Response rates (response rates will be assessed using the following subcategories: SD, MR, PR, VGPR [with subgroup nCR], CR, sCR, mCR). Response measured after induction, after intensification, after consolidation and during maintenance.
3. Toxicity ([serious] adverse events CTC grade 3 and grade 4, CTC-AE v4.0), measured at induction, consolidation and maintenance treatment

Completion date

11/03/2017

Eligibility

Key inclusion criteria

1. Confirmed diagnosis of multiple myeloma requiring systemic therapy
2. Measurable disease
3. Aged 18 - 70 years inclusive, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Previous chemotherapy or radiotherapy during the past 5 years except local radiotherapy in case of local myeloma progression
2. Severe cardiac dysfunction
3. Significant hepatic dysfunction
4. Patients known to be human immunodeficiency virus (HIV)-positive
5. Patients with active, uncontrolled infections
6. Patients with peripheral neuropathy or neuropathic pain, Common Toxicity Criteria (CTC) grade 2 or higher
7. Patients with a history of active malignancy during the past 5 years
8. Systemic amyloid light chain (AL) amyloidosis
9. Pregnancy and lactation

Date of first enrolment

26/07/2010

Date of final enrolment

14/11/2013

Locations**Countries of recruitment**

France

Germany

Study participating centre

Universitätsklinikum Heidelberg

Heidelberg

Germany

69120

Sponsor information

Organisation

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

ROR

<https://ror.org/013czdx64>

Funder(s)**Funder type**

Industry

Funder Name

Celgene (Europe)

Alternative Name(s)

Celgene Corporation

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Janssen Cilag (Europe)

Funder Name

Chugai (Germany)

Funder Name

The Binding Site (Germany)

Funder Name

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2015	29/01/2019	Yes	No
Results article		01/07/2020	10/02/2020	Yes	No
Other publications		11/11/2025	18/11/2025	Yes	No