

Lenalidomide and dexamethasone with or without high-dose melphalan and autologous blood stem cell transplantation followed by lenalidomide maintenance in the treatment of relapsed multiple myeloma

Submission date 24/08/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/10/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ReLApsE_RV-MM-GMMG-340

Study information

Scientific Title

A phase III national, multicentre, randomised open-label study with lenalidomide /dexamethasone versus lenalidomide/dexamethasone followed by high-dose chemotherapy melphalan with autologous blood stem cell transplantation and lenalidomide maintenance therapy for patients with relapsed multiple myeloma

Acronym

ReLApsE

Study hypothesis

The aim of this trial is to demonstrate a significant improvement of progression-free survival in patients treated with lenalidomide/dexamethasone induction therapy followed by high-dose chemotherapy melphalan and lenalidomide maintenance compared to conventional therapy with lenalidomide/dexamethasone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethikkommission der Medizinischen Fakultät Heidelberg, University of Heidelberg, 12/03/2010

Study design

Randomised open-label multicentre phase III trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

Relapsed multiple myeloma

Interventions

Patients are randomised into two treatment arms (A and B).

Standard arm A:

Rd until disease progression. Rd = lenalidomide 25 mg orally (po) days 1 - 21 and day 28 + dexamethasone 40 mg po day 1, 8, 15, 22 and 28.

Experimental arm B:

Induction therapy with 3 cycles Rd. Rd = lenalidomide 25 mg orally (po) days 1 - 21 and day 28 + dexamethasone 40 mg po day 1, 8, 15, 22 and 28. Then high dose melphalan (200 mg/m²) with autologous peripheral blood stem cell transplantation (PBSCT) followed by lenalidomide maintenance (10 mg/day) until disease progression.

The total duration of treatment is a maximum of 5 years, the end of trial is defined 2 years after inclusion of last patient in the trial.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Lenalidomide, dexamethasone, melphalan

Primary outcome measure

Progression-free survival: time from randomisation until disease progression or death from any cause whichever occurs first. This is measured at several timepoints during study and follow up if there is a progression of the disease.

Secondary outcome measures

1. Overall survival (time from randomisation until death from any cause or date last contact)
2. Response rate (subcategories: minimal response [MR], partial response [PR], very good partial response [VGPR], complete response [CR]), measured after third and fifth cycle Rd and every three months during maintenance (Arm A) and measured after third cycle Rd, after high dose melphalan and every three months during maintenance (Arm B)
3. Feasibility of stem cell collection
4. Assessment of safety and toxicity. measured from inclusion until 30 days after last dose
5. Time to initiation of new myeloma treatment

Overall study start date

27/09/2010

Overall study end date

30/06/2017

Eligibility

Participant inclusion criteria

1. Understand and voluntarily sign an informed consent form (aged greater than or equal to 18 years at time of signature)
2. Aged greater than or equal to 18 years and less than or equal to 70 years at time of

randomisation, either sex

3. Able to adhere to the study visit schedule and other protocol requirements
4. Patients with relapsed multiple myeloma (1.-3. relapse) Salmon-Durie-Stage II or III requiring systemic therapy
5. World Health Organization (WHO) performance status less than or equal to 2 at study entry
6. Results of laboratory assessments at time of inclusion within these ranges
 - 6.1. Absolute neutrophil count greater than or equal to $1.0 \times 10^9/L$
 - 6.2. Platelet count greater than or equal to $75 \times 10^9/L$ (if plasma cell infiltration of bone marrow less than 50%; platelets greater than or equal to $30 \times 10^9/L$ if plasma cell infiltration of bone marrow greater than or equal to 50%)
 - 6.3. Creatinine-Clearance greater than or equal to 30 mL/min
 - 6.4. Total bilirubin less than or equal to 2 x upper limit of normal (ULN) (unless myeloma related)
 - 6.5. Alanine aminotransferase (ALT) less than or equal to 3 x ULN (unless myeloma related)
7. Willing to adhere to requirements of Pregnancy Prevention Program
8. Disease free of other malignancies for greater than or equal to 5 years (exceptions include: basal cell carcinoma, carcinoma in situ of skin, cervix or breast)
9. Able to perform thromboprophylaxis with low molecular weight heparin
10. Patients who received high-dose chemotherapy and autologous stem cell transplantation in first-line therapy are eligible if they had no disease progression/relapse less than 12 months after transplantation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

282

Participant exclusion criteria

1. Pregnant or breast feeding female
2. Non-secretory myeloma (with normal FLC-ratio)
3. Systemic AL-amyloidosis with organ involvement (except for AL-amyloidosis of skin and/or bone marrow)
4. Received treatment with any non-market drug substance within 28 days prior to start of study treatment
5. Known hypersensitivity to thalidomide or to any constituent compounds of Lenalidomide (Revlimid, e.g. lactose)
6. Development of erythema nodosum, if characterised by a desquamating rash while taking thalidomide or similar drugs
7. Active uncontrolled infection
8. Known positivity for human immunodeficiency virus (HIV) or clinically active hepatitis B or C
9. Heart insufficiency New York Heart Association (NYHA) greater than or equal to 3
10. Any serious pulmonary, neurological or psychiatric disease

11. Patient with plasma cell leukaemia
12. Previous allogeneic transplantation
13. Previous therapy with lenalidomide
14. Previous salvage autologous transplantation

Recruitment start date

27/09/2010

Recruitment end date

30/06/2017

Locations

Countries of recruitment

Germany

Study participating centre

Universitätsklinikum Heidelberg

Heidelberg

Germany

69120

Sponsor information

Organisation

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

Sponsor details

Im Neuenheimer Feld 672

Heidelberg

Germany

69120

Sponsor type

Not defined

Website

<http://www.klinikum.uni-heidelberg.de/>

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

Dietmar-Hopp-Foundation (Germany)

Funder Name

Chugai (Germany)

Funder Name

Amgen (Germany)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	25/04/2016		Yes	No