ISRCTN16345835 https://doi.org/10.1186/ISRCTN16345835

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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/09/2010	**Overall study status** Completed	
Last Edited 06/10/2016	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Hartmut Goldschmidt

Contact details
Universitätsklinikum Heidelberg
Medizinische Klinik V und Nationales Centrum für Tumorerkrankungen (NCT)
Im Neuenheimer Feld 410
Heidelberg
Germany
69120

Additional identifiers

Protocol serial number
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 objectives
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 Fakultaet Heidelberg, University of Heidelberg, 12/03/2010

Primary study design
Interventional

Study design
Randomised open-label multicentre phase III trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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/m^2) 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(s)
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.

Key secondary outcome(s)
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

Completion date
30/06/2017

Eligibility

Key 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 x 10^9/L
6.2. Platelet count greater than or equal to 75 x 10^9/L (if plasma cell infiltration of bone marrow less than 50%; platelets greater than or equal to 30 x 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key 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

Date of first enrolment
27/09/2010

Date of final enrolment
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)

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

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