



Clinical trial results: Pomalidomide in relapsed and refractory multiple myeloma (RRMM) Summary

EudraCT number	2013-002101-62
Trial protocol	GB
Global end of trial date	13 October 2015

Results information

Result version number	v1 (current)
This version publication date	04 January 2020
First version publication date	04 January 2020
Summary attachment (see zip file)	Never opened to recruitment statement (Never opened to recruitment statement.docx)

Trial information

Trial identification

Sponsor protocol code	HM13/10758
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Additional study identifiers

ISRCTN number	ISRCTN24593488
ClinicalTrials.gov id (NCT number)	NCT02406222
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Leeds
Sponsor organisation address	Worsley Building, Leeds, United Kingdom, LS2 9JT
Public contact	Clare Skinner, University of Leeds, 0113 3434897, c.e.skinner@leeds.ac.uk
Scientific contact	Clare Skinner, University of Leeds, 0113 3434897, c.e.skinner@leeds.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 October 2015
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	13 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine whether the addition of cyclophosphamide to pomalidomide and dexamethasone (CPD) improves progression-free survival in patients with relapsed refractory myeloma (RRMM) in the UK, compared to pomalidomide and dexamethasone (Pd) alone.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

n/a

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Main Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

n/a

Arms

Arm title	Pomalidomide, cyclophosphamide and dexamethasone
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Pomalidomide, cyclophosphamide and dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Tablet, Tablet
Routes of administration	Oral use

Dosage and administration details:

All IMP's in the arm would have been administered orally.

Number of subjects in period 1	Pomalidomide, cyclophosphamide and dexamethasone
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Pomalidomide, cyclophosphamide and dexamethasone
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Reporting group description: -

Reporting group values	Pomalidomide, cyclophosphamide and dexamethasone	Total	
Number of subjects	99999	99999	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Pomalidomide, cyclophosphamide and dexamethasone
Reporting group description: -	

Primary: addition of cyclophosphamide to pomalidomide and dexamethasone (CPD) improves progression-free survival

End point title	addition of cyclophosphamide to pomalidomide and dexamethasone (CPD) improves progression-free survival ^[1]
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End point description:

this trial was discontinued with no participants enrolled in the trial.

End point type	Primary
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End point timeframe:

this trial was discontinued with no participants enrolled in the trial.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: this trial was discontinued with no participants enrolled in the trial.

End point values	Pomalidomide, cyclophosphamide and dexamethasone			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[2]			
Units: yes/no				

Notes:

[2] - this trial was discontinued with no participants enrolled in the trial.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

n/a- trial never opened to recruitment

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4.0
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Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: this trial was discontinued with no participants enrolled in the trial.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported