Clinical trial results:
Safety And Efficacy Of Lenalidomide As Maintenance Therapy In Patients With Newly Diagnosed Multiple Myeloma Following A Tandem Autologous-Allogeneic Transplant

Summary

EudraCT number	2008-004529-41
Trial protocol	IT
Global end of trial date	24 August 2023

Results information

Result version number	v1 (current)
This version publication date	21 October 2023
First version publication date	21 October 2023

Trial information

Trial identification

Sponsor protocol code	RV-MM-GITMO-413

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01264315
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fondazione EMN Italy Onlus
Sponsor organisation address	Via Nizza, 52, Turin, Italy, 10126
Public contact	Fondazione EMN Italy Onlus, Fondazione EMN Italy Onlus, 0039 0110243236, clinicaltrialoffice@emnitaly.org
Scientific contact	Fondazione EMN Italy Onlus, Fondazione EMN Italy Onlus, 0039 0110243236, clinicaltrialoffice@emnitaly.org

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	24 August 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To evaluate toxicity and tolerability of lenalidomide after allografting 2. To evaluate efficacy of lenalidomide in inducing complete remission, defined as negative immunofixation, 12 months after allografting.

Protection of trial subjects:

Under approval of Local Etical Commitee

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 August 2008
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	Italy: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	11
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The pre-treatment period includes screening visits, performed at study entry. After providing written informed consent to participate in the study, patients will be evaluated for study eligibility. The screening period includes the availability of inclusion criteria.

Pre-assignment

Screening details:

A conference will be held with the patient, donor and family to explain option of a tandem auto/allo approach. Inclusion and exclusion criteria will be evaluated.

Period 1

Period 1 title	Lenalidomide and Tandem Auto-Allo SCT (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

NA

Arms

Arm title	Lenalidomide Tandem Auto-Allo SCT

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide will be given orally at the dose of 25 mg/day for 21 days followed by a 7 day rest period (day 22 to 28)

Number of subjects in period 1	Lenalidomide Tandem Auto-Allo SCT
Started	12
Completed	0
Not completed	12
Adverse event, serious fatal	1
Lost to follow-up	9
Lack of efficacy	2

Baseline characteristics

Reporting groups

Reporting group title	Lenalidomide and Tandem Auto-Allo SCT

Reporting group description: -

Reporting group values	Lenalidomide and Tandem Auto-Allo SCT	Total	
Number of subjects	12	12	
Age categorical Units: Subjects			
Adults (18-64 years)	11	11	
From 65-84 years	1	1	
Age continuous Units: years			
median	56		
full range (min-max)	51 to 65	-	
Gender categorical Units: Subjects			
Female	6	6	
Male	6	6	

Subject analysis sets

Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat

Subject analysis set description:
ITT

Reporting group values	ITT		
Number of subjects	12		
Age categorical Units: Subjects			
Adults (18-64 years)	11		
From 65-84 years	1		
Age continuous Units: years			
median	56		
full range (min-max)	51 to 65		
Gender categorical Units: Subjects			
Female	6		
Male	6		

End points

End points reporting groups	
Reporting group title	Lenalidomide Tandem Auto-Allo SCT
Reporting group description: -	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description: ITT	

Primary: CR Rate	
End point title	CR Rate
End point description:	
End point type	Primary
End point timeframe: 12 months	

End point values	Lenalidomide Tandem Auto-Allo SCT	ITT		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	12		
Units: Patients	1	1		

Statistical analyses

Statistical analysis title	No statistical analysis
Statistical analysis description: No statistical analysis	
Comparison groups	Lenalidomide Tandem Auto-Allo SCT v ITT
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0 [2]
Method	No statistical analysis
Parameter estimate	No statistical analysis
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard deviation
Dispersion value	0

Notes:
[1] - No statistical analysis
[2] - No statistical analysis

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Per protocol	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26

Reporting groups	
Reporting group title	Per Protocol

Reporting group description: -

Serious adverse events	Per Protocol		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Per Protocol		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 11 (36.36%)		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	4		
Thrombocytopenia			
subjects affected / exposed	4 / 11 (36.36%)		
occurrences (all)	4		
Anaemia			
subjects affected / exposed	3 / 11 (27.27%)		
occurrences (all)	3		
General disorders and administration site conditions			

Fatigue subjects affected / exposed occurrences (all)	3 / 11 (27.27%) 3		
Mucosal inflammation subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 January 2010	Given the current availability of immunomodulatory drugs that can be used in induction before transplantation, this amendment intends to extend the enrollment in the protocol to patients who have used therapeutic regimens containing alternatively thalidomide, bortezomib or lenalidomide in the induction phase, based on the preferences and availability of the individual centre.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported