Clinical trial results:
STEM CELL TRANSPLANTATION FOR ERADICATION OF MINIMAL PANCREATIC CANCER PERSISTING AFTER SURGICAL EXCISION

Summary

EudraCT number	2012-003528-19
Trial protocol	DE
Global end of trial date	13 June 2016

Results information

Result version number	v1 (current)
This version publication date	11 March 2020
First version publication date	11 March 2020
Summary attachment (see zip file)	Statement STEM PACE 2012-003528-19 (Statement_STEM PACE_2012-003528-19.pdf)

Trial information

Trial identification

Sponsor protocol code	STEM PACE

Additional study identifiers

ISRCTN number	ISRCTN47877138
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ruprecht-Karls-University Heidelberg, Medical Faculty represented by Universitätsklinikum Heidelberg and Acting Business Director
Sponsor organisation address	Im Neuenheimer Feld 672, Heidelberg, Germany,
Public contact	Clinic of General Surgery, University Hospital Heidelberg, +49 62215639491,
Scientific contact	Clinic of General Surgery, University Hospital Heidelberg, +49 62215639491,

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 June 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 June 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The overall objective of this trial is to generate for the first time state-of-the-art scientific clinical evidence that allo-HSCT is feasible and can provide long-term disease control in patients with effectively resected pancreatic adenocarcinoma and may have the potential to change the natural course of this otherwise fatal malignancy.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 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:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Arm title	Allo-HSCT

Arm description:

allogeneic hematopoietic stem cell transplantation

Arm type	Experimental
Investigational medicinal product name	Allogeneic hematopoietic stem cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Number of subjects in period 1	Allo-HSCT
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	overall trial
Reporting group description:	
-	

Reporting group values	overall trial	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	
Age continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Allo-HSCT

Reporting group description:

allogeneic hematopoietic stem cell transplantation

Primary: 2-year progression-free survival (PFS) from registration.

End point title	2-year progression-free survival (PFS) from registration.[1]

End point description:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the Trial.

End point type	Primary

End point timeframe:

N/A

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: 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.
No statistical analyses for this end point.

End point values	Allo-HSCT			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: N/A	99999			

Notes:

[2] - No subjects were enrolled in the trial hence results are not available.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the clinical trial were to be collected.

Adverse event reporting additional description:

N/A

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Allo-HSCT

Reporting group description:

N/A

Serious adverse events	Allo-HSCT		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Allo-HSCT		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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: No subjects were enrolled in the trial hence results are not available .

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 April 2013	Clarifications and responses to subsequent demands of the Ethics Committee
29 July 2014	Change of Principal Inverstigator and update of inclusion and exclusion criteria

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in the Trial hence results are not available.

Notes: