Clinical trial results:
A Phase I/II safety and tolerability study following autologous infusion of adult haematopoietic cells to patients with acute total anterior circulation ischaemic stroke

Summary

EudraCT number	2006-000281-36
Trial protocol	GB
Global end of trial date	03 December 2012

Results information

Result version number	v1 (current)
This version publication date	08 February 2020
First version publication date	08 February 2020

Trial information

Trial identification

Sponsor protocol code	HHSC/003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00535197
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Jeremy Chataway, Imperial College London, +44 020 7886 6666 , Jeremy.Chataway@imperial.nhs.uk
Scientific contact	Jeremy Chataway, Imperial College London, +44 020 7886 6666 , Jeremy.Chataway@imperial.nhs.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	02 December 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 July 2012
Global end of trial reached?	Yes
Global end of trial date	03 December 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Safety and tolerability of infused immuno-selected CD34+ autologous adult haematopoietic stem cells

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2007
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: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	3
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started December 2007 at Imperial College Healthcare National HealthServices Trust.

Pre-assignment

Screening details:

Due to the low recruitment/screen ratio, the criteria were expanded from August 2010 onward to include the partial anterior circulation stroke (PACS) subtype of ischemic stroke.

Period 1

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

Arms

Arm title	CD34+ Stem/Progenitor Cell Therapy

Arm description:

Participants received CD34+ Stem/Progenitor Cell Therapy

Arm type	Experimental
Investigational medicinal product name	Immuno-selected CD34+ haematopoietic stem cells
Investigational medicinal product code	
Other name	Haematopoietic CD34+ stem cells
Pharmaceutical forms	Suspension for suspension for injection
Routes of administration	Intraarterial use

Dosage and administration details:

CD34+ cells were collected from the bone marrow of the subjects before being delivered by catheter angiography into the ipsilesional middle cerebral artery. Infusion of autologous CD34+ stem cells into middle cerebral artery: intra-arterial infusion into ipsilateral MCA, via trans-femoral approach. 1 x 10 to the 9 to cells/10mL

Number of subjects in period 1	CD34+ Stem/Progenitor Cell Therapy
Started	5
Completed	5

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	5	5	
Age categorical Units: Subjects			
Adults (Age 45-75)	5	5	
Age continuous Units: years			
arithmetic mean	58.2		
full range (min-max)	45 to 75	-	
Gender categorical Units: Subjects			
Female	2	2	
Male	3	3	

End points

End points reporting groups

Reporting group title	CD34+ Stem/Progenitor Cell Therapy
Reporting group description: Participants received CD34+ Stem/Progenitor Cell Therapy	
Subject analysis set title	Baseline
Subject analysis set type	Full analysis
Subject analysis set description: Baseline measurements	

Primary: Number of a Serious Adverse Event Related to the Treatment

End point title	Number of a Serious Adverse Event Related to the Treatment[1]
End point description: Safety will be evaluated in terms of adverse events graded according to CTC toxicity criteria and laboratory test results	
End point type	Primary
End point timeframe: 180 days	

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: No statistic is due to the nature of the primary outcome.

End point values	CD34+ Stem/Progenitor Cell Therapy			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Number of participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Changes in clinical function as assessed by the Modified Rankin Score

End point title	Changes in clinical function as assessed by the Modified Rankin Score
End point description: The scales with possible scores ranging from 0 to 5. Zero is no symptoms at all, 5 is dead.	
End point type	Secondary
End point timeframe: Day 0 (Baseline), day 180	

End point values	CD34+ Stem/Progenitor Cell Therapy	Baseline		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	5		
Units: score				
arithmetic mean (full range (min-max))	1.60 (0 to 3)	3.80 (3 to 5)		

Statistical analyses

Statistical analysis title	Modified Rankin Score
Comparison groups	CD34+ Stem/Progenitor Cell Therapy v Baseline
Number of subjects included in analysis	10
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0004
Method	t-test, 2-sided

Secondary: Changes in Clinical Function as Assessed by the NIH Stroke Scale

End point title	Changes in Clinical Function as Assessed by the NIH Stroke Scale
End point description:	
End point type	Secondary
End point timeframe: Day 0, Day 180	

End point values	CD34+ Stem/Progenitor Cell Therapy	Baseline		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	5		
Units: score				
arithmetic mean (full range (min-max))	2.20 (0 to 5)	10.40 (4 to 17)		

Statistical analyses

Statistical analysis title	NIH Stroke Scale
Statistical analysis description: Day 0 (baseline) compare to Day 180	
Comparison groups	CD34+ Stem/Progenitor Cell Therapy v Baseline

Number of subjects included in analysis	10
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	t-test, 2-sided

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

180 days

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Reporting groups

Reporting group title	CD34+ Stem/Progenitor Cell Therapy

Reporting group description:

Participants received CD34+ Stem/Progenitor Cell Therapy

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 non-serious adverse event occurred.

Serious adverse events	CD34+ Stem/Progenitor Cell Therapy		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 5 (20.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal dysfunction			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	CD34+ Stem/Progenitor Cell Therapy		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/25107583