Clinical trial results:
A prospective, randomised study to assess safety, changes in platelet reactivity, plasma cardiac biomarkers and metabolic parameters over 48 weeks in HIV-1 infected subjects undergoing a switch in antiretroviral therapy.

Summary

EudraCT number	2009-011538-93
Trial protocol	IE GB
Global end of trial date	29 March 2013

Results information

Result version number	v1 (current)
This version publication date	01 November 2019
First version publication date	01 November 2019

Trial information

Trial identification

Sponsor protocol code	Maraviroc_switch

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00981773
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	Prof Alan Winston, Imperial College London, +44 (0)20 3312 1603, a.winston@imperial.ac.uk
Scientific contact	Prof Alan Winston, Imperial College London, +44 (0)20 3312 1603, a.winston@imperial.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	29 March 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 March 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to determine whether switching from an antiretroviral regimen containing abacavir and / or didanosine to one containing maraviroc will lead to a reduction in platelet reactivity at 12 and 24 weeks thereby conferring a reduction in risk of heart attack.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2009
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: 17
Country: Number of subjects enrolled	Ireland: 1
Worldwide total number of subjects	18
EEA total number of subjects	18

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)	18
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled between September 2011 and March 2013, from St Marys Hospital (London, UK) and Mater Misericordiae University Hospital (Dublin, Ireland).

Pre-assignment

Screening details:

The initial aim was to recruit 40 subjects, however of the 31 subjects on boosted protease inhibitor containing regimens who were screened, 18 had CCR5-tropic virus of whom 6 were randomised to immediate and 12 to deferred switch.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Immediate switch

Arm description:

switch NRTI backbone to maraviroc 150 mg twice daily

Arm type	Active comparator
Investigational medicinal product name	maraviroc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150 mg twice daily

Arm title	Deferred switch

Arm description:

switch NRTI backbone to maraviroc 150 mg twice daily after `12 weeks

Arm type	Active comparator
Investigational medicinal product name	maraviroc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150 mg twice daily after 12 weeks

Number of subjects in period 1	Immediate switch	Deferred switch
Started	6	12
Completed	6	12

Baseline characteristics

Reporting groups	
Reporting group title	Immediate switch
Reporting group description: switch NRTI backbone to maraviroc 150 mg twice daily	
Reporting group title	Deferred switch
Reporting group description: switch NRTI backbone to maraviroc 150 mg twice daily after `12 weeks	

Reporting group values	Immediate switch	Deferred switch	Total
Number of subjects	6	12	18
Age categorical Units: Subjects			
Adults (18-64 years)	6	12	18
Age continuous Units: years			
median	54	48.6	
inter-quartile range (Q1-Q3)	38 to 54.6	43.0 to 54.0	-
Gender categorical Units: Subjects			
Female	2	5	7
Male	4	7	11
Baseline CD4 count Units: cells/uL			
median	678	528	
inter-quartile range (Q1-Q3)	383 to 903	341 to 598	-

Subject analysis sets	
Subject analysis set title	All participants
Subject analysis set type	Full analysis

Subject analysis set description:

Due to difficulties in recruitment (subjects were required to have CCR5 tropic HIV virus), lower numbers of participants than anticipated were recruited.
Analyses are therefore undertaken on the entire study population with no comparisons between study arms (before switch and after switch)

Reporting group values	All participants		
Number of subjects	18		
Age categorical Units: Subjects			
Adults (18-64 years)	18		
Age continuous Units: years			
median	49.4		
inter-quartile range (Q1-Q3)	42.4 to 54.2		

Gender categorical Units: Subjects			
Female	7		
Male	11		
Baseline CD4 count Units: cells/uL			
median	540		
inter-quartile range (Q1-Q3)	380 to 774		

End points

End points reporting groups

Reporting group title	Immediate switch
Reporting group description: switch NRTI backbone to maraviroc 150 mg twice daily	
Reporting group title	Deferred switch
Reporting group description: switch NRTI backbone to maraviroc 150 mg twice daily after `12 weeks	
Subject analysis set title	All participants
Subject analysis set type	Full analysis
Subject analysis set description: Due to difficulties in recruitment (subjects were required to have CCR5 tropic HIV virus), lower numbers of participants than anticipated were recruited. Analyses are therefore undertaken on the entire study population with no comparisons between study arms (before switch and after switch)	

Primary: Percentage changes in adenosine diphosphate (ADP) before and after switch

End point title	Percentage changes in adenosine diphosphate (ADP) before and after switch[1]
End point description:	
End point type	Primary
End point timeframe: 12 weeks	

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 statistical analyses due to the low number of participants.

End point values	All participants			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: uM				
number (confidence interval 95%)	9 (-6 to 24.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Changes in D-dimer 12 weeks after switch

End point title	Changes in D-dimer 12 weeks after switch
End point description:	
End point type	Secondary
End point timeframe: 12 weeks	

End point values	All participants			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: g/L				
median (confidence interval 95%)	-0.029 (-0.14 to 0.08)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 12 weeks	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10

Reporting groups	
Reporting group title	All participants
Reporting group description: -	

Serious adverse events	All participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 18 (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: It was no non-serious adverse event

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