Clinical trial results:
A randomised, open label, prospective study to assess two different therapeutic strategies following first treatment failure in HIV-1 infected subjects.
'The First Failure Study' : 'FAST'

Summary

EudraCT number	2009-011816-39
Trial protocol	GB
Global end of trial date	28 April 2014
Results information	
Result version number	v1 (current)
This version publication date	28 December 2019
First version publication date	28 December 2019
Summary attachment (see zip file)	Prematurely Ended (declaration_end_trial_form_FAST study 22Nov19.pdf)

Trial information

Trial identification	
Sponsor protocol code	13SM1317
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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	Alan Winston-OKeefe, Imperial College London, a.winston@imperial.ac.uk
Scientific contact	Alan Winston-OKeefe, Imperial College London, 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	28 April 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 April 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This study will assess important clinical and laboratory differences between these two therapeutic options. Potential differences between two such treatment approaches include differences in body fat distribution, in blood fat levels, in adherence and in neurocognitive function.
The primary objective is to measure the changes from baseline in peripheral and central body fat, as measured by DEXA scan at weeks 48 and 96 between the treatment arms.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2010
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:

This trial was prematurely ended due to failure to recruit participants. 99999 is "Not applicable" value or 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Overall 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	4 active comparator drugs and a placebo

Arm description: -

Arm type	Trial ended prematurely
Investigational medicinal product name	Trial ended prematurely
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

N/A

Number of subjects in period 1	4 active comparator drugs and a placebo
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial (overall period)

Reporting group description: -

Reporting group values	Overall Trial (overall period)	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	4 active comparator drugs and a placebo

Reporting group description: -

Primary: Mean change from baseline in peripheral and central adipose tissue, as measured by DEXA, at weeks 48 and 96 between treatment arms

End point title	Mean change from baseline in peripheral and central adipose tissue, as measured by DEXA, at weeks 48 and 96 between treatment arms[1]

End point description:

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: The trial ended prematurely due to insufficient recruitment numbers so statistical analysis was done.

End point values	4 active comparator drugs and a placebo			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: Units	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

N/A

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	4 active comparator drugs and a placebo

Reporting group description: -

Serious adverse events	4 active comparator drugs and a placebo		
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			

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

Non-serious adverse events	4 active comparator drugs and a placebo		
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: The trial ended prematurely due to insufficient recruitment numbers so no adverse events occurred.

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

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

The trial ended prematurely due to insufficient recruitment. 99999 is "Not applicable" value or 0 participants.

Notes: