Clinical trial results:
A PROSPECTIVE, RANDOMIZED, CONTROLLED AND PILOT STUDY TO ASSESS THE EFFICACY AND SAFETY OF SAQUINAVIR/RITONAVIR MONOTHERAPY vs HAART THERAPIES AS A NEW NUCLEOSIDE-SPARING MAINTENANCE STRATEGY.

Summary

EudraCT number	2006-001136-47
Trial protocol	ES
Global end of trial date	14 May 2008

Results information

Result version number	v1 (current)
This version publication date	09 August 2017
First version publication date	09 August 2017

Trial information

Trial identification

Sponsor protocol code	SQV/RTV-MONOTERAPIA

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00379405
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Lluita contra la SIDA
Sponsor organisation address	Crta de Canyet s/n, Badalona, Spain, 08916
Public contact	CRA, Fundació Lluita contra la SIDA, +34 93 497 84 14, jtoro@flsida.org
Scientific contact	CRA, Fundació Lluita contra la SIDA, +34 93 497 84 14,

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	14 May 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 May 2008
Global end of trial reached?	Yes
Global end of trial date	14 May 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy and safety of saquinavir/ritonavir monotherapy twice daily (as a nucleoside-sparing maintenance strategy), compare to HAART therapies.

Protection of trial subjects:

not specific

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 July 2006
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	Spain: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

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)	28
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 28 patients were enrolled

Pre-assignment

Screening details:

Participants were randomized in a 2:1 ratio

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	SQV/r group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Saquinavir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 1000 mg twice daily	
Investigational medicinal product name	ritonavir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 100 mg twice daily	
Arm title	control group
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	SQV/r group	control group
Started	17	11
Completed	13	10
Not completed	4	1
Adverse event, non-fatal	2	-
virological failure	1	-

Lost to follow-up	-	1
voluntary discontinuation of therapy	1	-

Baseline characteristics

Reporting groups	
Reporting group title	SQV/r group
Reporting group description: -	
Reporting group title	control group
Reporting group description: -	

Reporting group values	SQV/r group	control group	Total
Number of subjects	17	11	28
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	17	11	28
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	44	42	
standard deviation	± 8.13	± 10.72	-
Gender categorical Units: Subjects			
Female	2	0	2
Male	15	11	26

End points

End points reporting groups

Reporting group title	SQV/r group
Reporting group description: -	
Reporting group title	control group
Reporting group description: -	

Primary: patients who maintained virological suppression in plasma

End point title	patients who maintained virological suppression in plasma[1]
End point description:	
End point type	Primary
End point timeframe:	
week 48	

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: Only 1 patient from the SQV/r group experienced virological failure at week 48. No need of comparison

End point values	SQV/r group	control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	11		
Units: percentage				
number (not applicable)	96.4	100		

Statistical analyses

No statistical analyses for this end point

Secondary: changes in CD4+ T-cell counts

End point title	changes in CD4+ T-cell counts
End point description:	
End point type	Secondary
End point timeframe:	
from baseline to week 48	

End point values	SQV/r group	control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	11		
Units: cels/mm3				
number (not applicable)				
baseline	838	552		
week 48	869	604		

Statistical analyses

Statistical analysis title	Comparing mean at baseline
Comparison groups	SQV/r group v control group
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.053
Method	t-test, 2-sided

Secondary: changes in HDL cholesterol

End point title	changes in HDL cholesterol

End point description:

End point type	Secondary

End point timeframe:
from baseline to week 48

End point values	SQV/r group	control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	11		
Units: mg/dL				
number (not applicable)				
baseline	41	40		
week 48	56	46		

Statistical analyses

Statistical analysis title	Comparing mean at week 48
Comparison groups	SQV/r group v control group

Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.314
Method	t-test, 2-sided

Secondary: changes in total cholesterol

End point title	changes in total cholesterol

End point description:

End point type	Secondary

End point timeframe:
from baseline to week 48

End point values	SQV/r group	control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	11		
Units: mg/dL				
number (not applicable)				
baseline	200	192		
week 48	198	187		

Statistical analyses

Statistical analysis title	Comparing mean at week 48
Comparison groups	SQV/r group v control group
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.41
Method	t-test, 2-sided

Secondary: changes in LDL cholesterol

End point title	changes in LDL cholesterol

End point description:

End point type	Secondary

End point timeframe:
from baseline to week 48

End point values	SQV/r group	control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	11		
Units: mg/dL				
number (not applicable)				
baseline	127	129		
week 48	127	107		

Statistical analyses

Statistical analysis title	Comparing mean at week 48
Comparison groups	SQV/r group v control group
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.114
Method	t-test, 2-sided

Secondary: changes in triglycerides

End point title	changes in triglycerides
End point description:	
End point type	Secondary
End point timeframe: from baseline to week 48	

End point values	SQV/r group	control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	11		
Units: mg/dL				
number (not applicable)				
baseline	155	144		
week 48	116	150		

Statistical analyses

Statistical analysis title	Comparing mean at week 48
Comparison groups	SQV/r group v control group
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.376
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: from baseline to week 48	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	DAIDS AE GRADING TAB
Dictionary version	1.0

Reporting groups	
Reporting group title	SQV/r group

Reporting group description: -

Serious adverse events	SQV/r group		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 17 (5.88%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Hepatobiliary disorders			
acute hepatitis B			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	SQV/r group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 17 (5.88%)		
Hepatobiliary disorders			
2-fold increase in transaminase			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 March 2006	co-investigator added
16 May 2006	monitor changed
26 September 2006	exclusion criteria number 7 modified

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported