Clinical trial results:
Pilot simplification study to Lopinavir/ritonavir 800/200 mg monotherapy regimen once daily

Summary

EudraCT number	2011-005981-39
Trial protocol	ES
Global end of trial date	10 February 2014

Results information

Result version number	v1 (current)
This version publication date	19 November 2021
First version publication date	19 November 2021

Trial information

Trial identification

Sponsor protocol code	KMON

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Unidad de VIH-Hospital de Bellvitge
Sponsor organisation address	Feixa Llarga s/n, Barcelona, Spain, 08907
Public contact	Antonio Navarro, Unidad de VIH. Servicio de Enfermedades Infecciosas. Hospital de Bellvitge, 0034 9333590117320, anavarroa@bellvitgehospital.cat
Scientific contact	Antonio Navarro, Unidad de VIH. Servicio de Enfermedades Infecciosas. Hospital de Bellvitge, 0034 9333590117320, anavarroa@bellvitgehospital.cat

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	03 March 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy in the control of viral replication (Viral load < 40 copies /ml)

Protection of trial subjects:

the sponsor contracted an insurance as a mandatory aspect defined in the legal framework of the country site due a different procedures performed during the clinical trial out of routine clinical practice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 April 2012
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: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	21
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects who met inclusion criteria and accepted to sign the informed consent to participate will be cited for a screening visit. A total of 21 HIV-infected patients were enrrolled. Recruitment was started 08-May-2012 and the last patient recruited was 11-mar-2013.

Pre-assignment

Screening details:

21 patients were screening and enrolled.

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	LPV/r

Arm description:

A HIV monotherapy treatment based on Lopinavir boosted with ritonavir

Arm type	Experimental
Investigational medicinal product name	Lopinavir/ritonavir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

800 mg of Lopinavir, 200mg ritonavir per day

Number of subjects in period 1	LPV/r
Started	21
Completed	21

Baseline characteristics

End points

End points reporting groups

Reporting group title	LPV/r
Reporting group description:	
A HIV monotherapy treatment based on Lopinavir boosted with ritonavir	

Primary: HIV-1 RNA plasma suppression

End point title	HIV-1 RNA plasma suppression[1]
End point description:	
End point type	Primary
End point timeframe:	
w48	

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: Justification: Data reported has been a descriptive analysis, which shows the % of patients with HIV-1 RNA suppression after treatment switch

End point values	LPV/r			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: %				
number (not applicable)	85.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Lopinavir/ritonavir cerebrospinal fluid concentrations

End point title	Lopinavir/ritonavir cerebrospinal fluid concentrations
End point description:	
End point type	Secondary
End point timeframe:	
w24	

End point values	LPV/r			
Subject group type	Reporting group			
Number of subjects analysed	9[2]			
Units: ng/mL				
median (inter-quartile range (Q1-Q3))	9.78 (1.9 to 78.3)			

Notes:

[2] - This endpoint was assessed in 9 patients only who were enrrolled in CSF sub-study

Statistical analyses

No statistical analyses for this end point

Secondary: Lopinavir/ritonavir plasma concentration

End point title	Lopinavir/ritonavir plasma concentration

End point description:

End point type	Secondary

End point timeframe:

w24

End point values	LPV/r			
Subject group type	Reporting group			
Number of subjects analysed	9[3]			
Units: ng/mL				
median (inter-quartile range (Q1-Q3))	1970 (154 to 16700)			

Notes:

[3] - This endpoint was assessed only in 9 patients who were enrrolled in a sub-study

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse event were reported since baseline visit to w48 and follow-up visit	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17

Reporting groups	
Reporting group title	LPV/ritonavir arm
Reporting group description:	
All participants were assessed for this adverse event	

Serious adverse events	LPV/ritonavir arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	LPV/ritonavir arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 21 (4.76%)		
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		

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 study limitations were a small sample size, the absence of a control arm and also the fact that neurocognitive assessments or inflammatory biomarkers in CSF were not carried out

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26656921