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EU Clinical Trials Register

Clinical trial results: *Full title of Trial**

Summary

EudraCT number*	2006-005996-17
Trial protocol	Lopinavir/Ritonavir Monotherapy Versus Standard Highly Active Antiretroviral Therapy (HAART) in HIV/HCV Coinfected Antiretroviral (ARV) Naïve Patients Starting Treatment With Anti-HCV Therapy (KAMON 1)
Global end of trial date*	2011-02-2

Trial information

Trial identification

Sponsor protocol code*	IRCCS-San Raffaele (KAMON 1)

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	00437476
WHO universal trial number (UTN)	-

Notes:

Sponsors details*

Sponsor organisation name	IRCCS Ospedale San Raffaele
Sponsor organisation address	Via Olgettina, 60, Milano, Italy, 20132
Public contact	Uberti Caterina uberti.caterina@hsr.it Sabrina Bagaglio bagaglio.sabrina@hsr.it
Scientific contact	Prof. Adriano Lazzarin

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?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Results analysis stage

Analysis stage*	Final
Date of interim/final analysis*	20 Mar 2012
Is this the analysis of the primary completion data?*	Yes
Global end of trial reached?*	Yes
Global end of trial date*	02 Feb 2011
Was the trial ended prematurely?	Yes

General information about the trial

Main objective of the trial*: *Enter a description for the mail objective(s) of the trial*

Actual start date of recruitment*	28 feb 2007
Long term follow-up planned*	No
If Yes, rationale: NA	Safety Efficacy Ethical reason Regulatory reason Scientific research
Duration	Years 4
Independent data monitoring committee (IDMC) involvement?*	Yes
Protection of trial subjects*:	The patients were followed up for 72 weeks (48 weeks of concomitant HIV/HCV therapy, followed by 24 weeks of HIV treatment alone), and evaluated after 2, 4, 8, 12, 24, 48, 60 and 72 weeks.
Background therapy:	
Evidence for comparator:	

Population of trial subjects

Subjects enrolled per country

Country:	ITALY
Planned number of subjects	10
Actual Number of subjects enrolled*	8 IRCCS Ospedale San Raffaele
Worldwide total number of subjects	30
EEA total number of subjects	

Subjects enrolled per age group

In utero*	NA
Preterm newborn - gestational age < 37wks*	NA
Newborns (0-27 days)*	NA
Infants and toddlers (28 days-23months)*	NA
Children (2-11 years)*	NA
Adolescents (12-17 years)*	NA
Adults (18-64 years)*	8
From 65 to 84 years*	NA
85 years and over*	NA

Subject disposition

Recruitment details: *Enter key information relevant to the recruitment process for the trial (eg gates of recruitment period and territories)*

- **Serologic evidence of HIV infection by HIV antibody and HIV-*RNA detection***
- ***Serologic evidence of HCV infection by HCV antibody and HCV-RNA detection***
- ***Subject is naïve for HIV and HCV therapy***

Pre-assignment - *Screening details**: Enter relevant information related to screening (eg screening criteria, significant events and approaches)*

Period 1	
Period title*	*Enter a title describing the stage of the trial. If the only one period is defined, the default title should be "Overall Trial"*
Is this the baseline period?	Yes or No
Allocation method*	Randomised - controlled Multicenters
Blinding used*	Not blinded

Arms	
Arm title*	*LPV/r*
Arm description:	*Lopinavir/Ritonavir 200/50 mg 2 cpr BID*
Arm type*	Intervention/Treatment
Investigational medicinal product name*	**KALETRA/ritonavir**
Investigational medicinal product code	
Other name	
Pharmaceutical forms*	**cpr**
Routes of administration*	**oral**
Dosage and administration details*	200/50 mg 2 cpr BID

Number of subjects in period	Arm Title (overall population)	Arm Title *(repeat for each arms if applicable)*
Started*	8	
Completed*	8	
Subject non-completion reason (if applicable)		
AE, non fatal		
AE, fatal		
Consent withdrawn by subject		
Lack of efficacy		
Lost to follow up		
Physician decision		
Pregnancy		
Protocol Deviation		
Other		

Baseline characteristics

Reporting groups* Overall cohort	
Reporting group title*	
Number of subjects at the baseline*	

Reporting group description: Please see table 1

TABLE 1 - *Haematological, immunovirological and pharmacokinetic characteristics of the patients in the two study arms*

Characteristics	*Baseline*			*48 weeks*			*72 weeks*		
	Arm A	*Arm B*	*P value*	*Arm A*	*Arm B*	*P value*	*Arm A*	*Arm B*	*P value*
Haemoglobin, g/dL	14 (13-14.5)	15.3 (14-16)	0.017	11 (11-12.3)	12 (11.6-13)	0.059	13 (12.4-14)	14 (12.4-15)	0.085
WBC, x10^3 cells/µL	6 (4.8-7)	5.85 (5.1-7.3)	0.793	2.7 (1.8-3.7)	3 (1.8-5)	0.339	5.5 (3.7-7)	5 (3.7-6.5)	0.958
ANC, x10^3 cells/µL	3 (2.5-3.5)	2.8 (2.4-4.5)	0.615	1.4 (1.0-1.7)	1.5 (0.9-2.8)	0.395	2.8 (1.9-4.2)	2.5 (1.9-5.01)	0.676
CD4 count, cells/µL	585 (399-806)	524 (433-749)	0.619	267 (183-474)	321 (272-432)	0.384	556 (340-633)	456 (417-553)	0.305
HCV RNA, Log IU/mL	6.18 (5.71- 6.46)	5.37 (4.24-6.32)	0.159	1.04 (1.04-4.52)	1.04 (1.04-2.69)	0.539	1.04 (1.04-4.86)	1.04 (1.04-4.29)	0.984
HIV RNA, copies/mL	49 (49-49)	49 (49-49)	0.351	49 (49-49)	49 (49-49)	0.351	49 (49-49)	49 (49-49)	0.407
Lopinavir C_{trough}, ng/mL	5529 (4506-6839)	7114 (5323-8449)	0.431	6330 (3919-6900)	6805 (5400-10000)	0.438	5573 (3268-6796)	5688 (4267-8177)	0.447

WBC = White Blood Cells; ANC = Absolute Neutrophil Count. Median (Q1-Q3) value or frequency (%).

Subject analysis sets

Add a subject analysis set if you wish to report on groups different from the reporting group defined above (repeat if applicable)

Subject analysis set title*	
Subject analysis set type*	Full Analysis **Intention to treat X** Per protocol Safety analysis Sub-group analysis
Subject analysis set description*	The primary statistical analysis (safety and immunovirological parameters) was made using the intention-to-treat (ITT) principle and the last observation carried forward (LOCF) method, whereas the analysis of virological efficacy was made using the on-treatment (OT) principle. The results are given as median values and interquartile ranges (IQR) or frequencies (%), as appropriate.
Number of subjects in subjects analysis set*	*8*

Age characteristics*

Complete either the age categorical, age continuous or complete both these characteristics in order to collect values for the reporting groups and optionally the subject analysis sets.

	Characteristic title*	Units*	Age categories*
Age categorical	44 arm A vs 48 arm B	years	42-46 45-53

	Characteristic title*	Units*	Central tendency*	Dispersion type*
Age continuous	Overall cohort	Years Months Weeks Days	Arithmetic Mean Median least square mean geometric mean log mean	full range (min-max) standard deviation inter quartile range

Gender characteristics*

	Characteristic title*	Units*	Gender categories*
Gender categorical	Males arm A 10 (67%) Vs arm B 11 (73%)	%	Female Male

Study specific characteristics NA

	Characteristic title*	Units *	Categories*	Number of subject for each categories
Study specific categorical				
Study specific categorical				
Study specific categorical				
Study specific categorical				
Study specific categorical				

End points

Add subject analysis set if you wish to report on groups different form reporting groups defined above

Subject analysis set title*	
Subject analysis set type*	Full Analysis **Intention to treat X** Per protocol **Safety analysis X** Sub-group analysis
Subject analysis set description*	To assess if the combination of PPV/r monotherapy in association with anti HCV therapy does not match with additional toxicity induced by the combination of optimized HAART (Lopinavir/ritonavir + selected Nucs) and PEG-IFN alfa 2a+Ribavirin

Number of subject in subject analysis set *	8

End points definitions

End point title*		
		Values
Countable or measurable?*	measurable	-
If countable, Countable units*:		
If measurable, Measurable units*		
Measure type*:	**Number X** Arithmetic Mean **Median X** least square mean geometric mean log mean	
Precision/dyspersion type*	NO	

End point type*	Primary Secondary

End point timeframe*: month

Use categories only if the data for the end point can be categorized

Category title

Specify the groups of subjects applicable to this end point

Reporting groups*	LPV/r	HAART	
Period	26 weeks	24 weeks	
Arms	A	B	
subject analysis sets	INT to treat	INT to treat	

Adverse events

Adverse events information

Timeframe for reporting adverse events*: *Enter the time point(s) or time period for AE assessment*

First patient first visit: 28/02/2007
Last recruitment date:
Study closure: 02/02/2011

Adverse event reporting additional description: *Enter information about the AE collection and provide details about the method of assessment and monitoring*

There was a total of 114 AEs (a median of 4 [2-5] per patient): 71 (4.5 [3-5]) in arm A, and 43 (3 [2-4]) in arm B. There were no significant between-group differences in the proportion of patients experiencing at least one AE (p=0.999) or in the number of AEs (p=0.146).
Nine patients experienced 14 grade 3-4 AEs: five in arm A (four cases of anemia and two of neutropenia), and four in arm B (three cases of neutropenia, two of anemia, and one case each of thrombocytopenia, rash and fatigue).

Assessment type*	Systematic
Frequency threshold for reporting non-serious adverse events*	*Enter the frequency of non SAE that are reported in the results database for all arms or reporting groups*

Dictionary used

Dictionary name*	MedDRA J05AR10
Dictionary version*	

Adverse events reporting group definition

Use arms from baseline period as reporting groups NOT APPLICABLE
OR

Reporting group title*: *Overall cohort*

For this reporting group, provide the following totals:

Subject exposed*	
Subjects affected by non -SAE*	
Total number of deaths (all causes)*	
Total number of deaths resulting from adverse event*	

Serious adverse event details and values NOT APPLICABLE

System organ class*:

Event term*:

Values for serious adverse event per reporting group * NOT APPLICABLE

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number	Occurrences causally related to treatment number	Fatalities number	Fatalities causally related to treatment number

Non - Serious adverse event details and values

System organ class*:

Event term*:

Values for non-serious adverse event per reporting group*

Threshold for non-serious adverse event reporting is:

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol*? Yes or No

Date	Amendment
04 Oct 2007	1.1 Version

Notes:

Interruptions (globally)

Were there any global interruptions to the trial*? **Y e s**

If Yes, Interruption date

Interruption descrption ; LOW RECRUITMENT

Limitations and caveats

The following publication referred to KAMON 1 and KAMON 2 Studies.

Online references

Enter PubMed identifier (PMID)

PMID:23109014
HAART simplification with lopinavir/ritonavir monotherapy in HIV/HCV co-infected patients starting anti-HCV treatment: a randomised pilot study (KaMon study).
Hasson H, Galli L, Gallotta G, Neri V, Blanc P, D'Annunzio M, Morsica G, Sollima S, Merli M, Lazzarin A, Uberti-Foppa C.New Microbiol. 2012 Oct;35(4):469-74. Epub 2012 Oct 1.PMID: 23109014 Free article. Clinical Trial.
The aim of this randomised, prospective, open-label, multicentre pilot clinical trial was to compare the 48-week toxicity profile of lopinavir/ritonavir (LPV/r) monotherapy with LPV/r-based HAART (KaMon = Kaletra monotherapy) in HIV/HCV patients undergoing HCV treatment. T …

Bagaglio S, Uberti-Foppa C, Di Serio C, Trentini F, Andolina A, Hasson H, Messina E, Merli M, Porrino L, Lazzarin A, Morsica G. Dynamic of Mixed HCV Infection in Plasma and PBMC of HIV/HCV Patients Under Treatment With Peg-IFN/Ribavirin. Medicine (Baltimore). 2015 Oct;94(43):e1876. doi: 10.1097/MD.0000000000001876. PMID: 26512601; PMCID: PMC4985415.