Poster O-07

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HCV treatment with Peg-IFN+Ribavirin in patients receiving Lopinavir/r as monotherapy or in triple therapy. PEKARI Study (GESIDA5506) interim analysis

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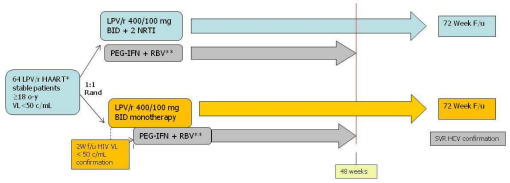
Background

- Anti-HCV therapy (pegylated interferon+ribavirine) has multiple side effects.
- The effectiveness of anti-HCV therapy is diminished in HIV/HCV coinfected subjects and the side effects play an important role.
- Lopinavir/ritonavir as a single antiretroviral drug use simultaneously with the anti-HCV therapy (pegylated interferon+ribavirine) could:
  - avoid the interactions between ribavirine and nucleosides and diminish mitochondrial toxicity and anaemia;
  - avoid the CNS symptons of efavirenz added to peg-IFN;
  - avoid the hepatotoxic effects of nevirapine.

Trial design

- The PEKARI study (GESIDA 5506) is a pilot, multicenter, randomized, open-label study to asses concomitant HCV and HIV Treatment with Peg-IFN+ Ribavirin in Patients Receiving Lopinavir/r as Monotherapy for HIV
- Approved by IEC and the Spanish NCA
- ClinicalTrials.gov identifier: NCT00866021
- Week 24 interim analysis



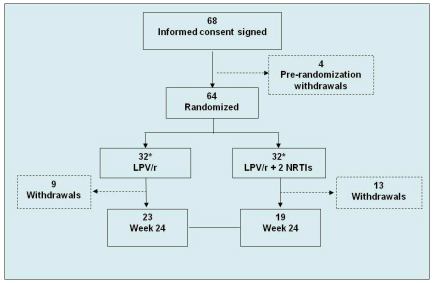
*Patients who were not on LPV/r containing HAART were switched to LPV/r 4 weeksprior to randomisation
** PegIFN α2a 180 mcg/w or α2b; RBV dose was adjusted according to HCV genotype

Baseline characteristics

	PegIFN+RBV	
	LPV/r (n=31)	LPV/r+2 NRTI (n=31)
Male, n (%)	19 (61.3)	25 (80.6)
Mean age, y	44.2	44.5
Current or past IV drug use, n (%)	29 (93.5%)	24 (77.4%)
Median time of HIV infection, y	17.3	14.6
Median nadir CD4, cells/mm^3	156	157
Median time of HCV infection, y	14.2	12.1
Median HCV RNA, $\log_{10}$ IU/mL	6.6	6.2
Median CD4 baseline, cells/mm^3	646	493
AIDS, n %	19 (61.3%)	24 (77.4%)
Median time on HAART, y	9.5	8.0
HCV genotype, n (%)	1: 17 (54.9%) 3: 9 (29.0%) 4: 5 (16.1%)	1: 18 (60%) 3: 11 (36.7%) 4: 1 (3.3%)
Fibrosis stage (FibroScan). N (%)	F0-1: 9 (31.0%) F2: 6 (20.7%) F3/F4 : 14 (48.2%)	F0-1: 12 (41.4%) F2: 7 (24.1%) F3/F4: 10 (34.5%)

P= NS for all comparisons between arms

Patients disposition



Patients withdrawal post randomization

	Peg-IFN+RBV	
	LPV/r	LPV/r+2NRTIs
TOTAL	9	13
HCV treatment failure, n	2	2
Drug use, n	1	2
Medication intolerance, n	1	1
Lost follow up, n	0	1
IC withdrawal, n	2	5
AEs: n	2	1
- Trombocitopaenia	2	0
- Ictericia due to haemolytic anaemia	0	1
Protocol violation, n (detectable HIV VL at randomization) *	1	0
Withdrawal before starting HCV theapy* n	0	1

Week-24 preliminary results (ITT)

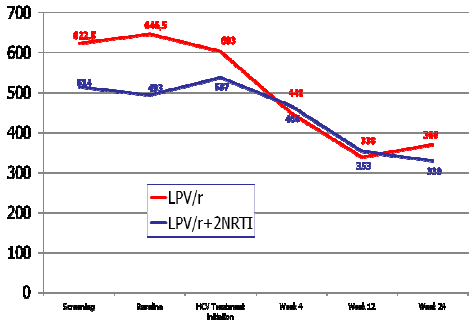
	PegIFN+RBV	
	LPV/r	LPV/r+2NRTIs
Total analysed, n	31	31
HCV VL < 50 week 4, n (%)	9 (29.0)	10 (32.3)
HCV VL < 50 week 12, n (%)	14 (45.2)	16 (51.6)
HCV VL reduction > 2 $\log_{10}$ week 12, n (%)	23 (74.2)	18 (58.1)
HCV VL <50 IU/mL week 24, n (%)	18 (58.1)	18 (58.1)

P= NS for all comparisons between arms

	Peg-IFN+RBV	
	LPV/r	LPV/r+2NRTIs
Total analysed, n	31	31
HIV VL<50 c/mL along 24 weeks, n (%)	26 (83.9)	30 (96.8)
HIV VL <50 c/ml at 24 week, n (%)	27 (87.1)	30 (96.8)
HIV confirmed virological failures, n	1	1
HIV Blips, n	3	0
Median CD4 change, cells/mm^3	-234	-198
Median CD4 change, %	- 4.0	- 5.0

P= NS for all comparisons between arms

Mean CD4 evolution (ITT)



Conclusions

- **In this 24 weeks interim analsys, the use of LPV/r in monotherapy on HIV/HCV co-infected patients being treated for HCV, was at least as effective as the use of a LPV/r containg HAART regimen.**
- **As previously described, HIV blips were more commonly observed in the LPV/r monotherapy arm but there were no more virological failure neither resistance mutations.**
- **Based on these results the study is continuing as planned up to 72 weeks follow up.**

The PEKARI (GESIDA5506) Study Team

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