Clinical trial results:
An open label, randomised, pilot trial of pegylated interferon, ribavirin and telaprevir versus pegylated interferon and ribavirin alone in the response guided treatment of acute hepatitis C genotype 1 virus infection in patients with HIV-1 co-infection

Summary

EudraCT number	2012-005525-75
Trial protocol	GB
Global end of trial date	29 February 2016

Results information

Result version number	v1 (current)
This version publication date	16 November 2017
First version publication date	16 November 2017

Trial information

Trial identification

Sponsor protocol code	SSAT052

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02006745
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	St Stephens Aids Trust
Sponsor organisation address	Chelsea Chambers, 262a Fulham Road, London, United Kingdom, SW10 9NH
Public contact	Marita Marshall, Head of Project Management, St Stephen's Clinical Research, +44 0203 828 0567, marita.marshall@ststcr.com
Scientific contact	Prof Mark Nelson, St Stephan’s Centre, Chelsea & Westminster Hospital, +44 0203 315 5610 , mark.nelson@chelwest.nhs.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	14 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 February 2016
Global end of trial reached?	Yes
Global end of trial date	29 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To find out whether treating acute hepatitis C infection with PEGylated interferon, ribavirin and telaprevir gets rid of the virus as effectively as when acute hepatitis C infection is treated with PEGylated interferon and ribavirin alone

Protection of trial subjects:

The protocol was written, and the study was conducted according to ICH GCP & the principles of the Declaration of Helsinki. The protocol was approved by the National Regulator & an Independent Ethics Committee as required by national legislation.

Written informed consent was obtained from each subject prior to evaluations being performed for eligibility.
The inclusion/exclusion criteria were designed to eliminate subjects who may have been put at risk by participating in the study. Safety & tolerability of medications were assessed by questions, physical examination & laboratory parameters. Any changes in health status during the study were recorded and followed up by the clinical team.

Female patients of childbearing potential & their male partners were required to use 2 effective contraceptive methods during treatment (as agreed by the investigator including a barrier method of contraception) and for at least 6 months after the last treatment (i.e. 6 months after week 12, 24 or 48, depending on study arm and treatment response). Routine monthly pregnancy tests were also required during this time and for 6 months after the end of treatment.

Heterosexually active male participants or their female partners were required to use 2 effective contraceptive methods during the trial and for at least 7 months after the last dosage of treatment.

Glucose monitoring was added to study procedures in line with information arising in an update to the SPC for Pegasys® during the study.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	13 May 2013
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: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

20 adult male & female HIV-1 positive patients with current documented acute hepatitis C genotype 1 infection with an estimated duration of <24 weeks at diagnosis, were recruited from the out-patient clinics at Chelsea & Westminster Hospital NHS Foundation Trust between 21/01//2014 & 20/10/2016.

Pre-assignment

Screening details:

24 patients were screened. There were a total of 6 screen failures. 2 of the screen failures underwent a second screening and were recruited to the study. Following successful screening, eligible patients were randomised at the baseline visit to treatment arm 1 or 2 in a 1:1 ratio.

Pre-assignment period milestones

Number of subjects started	24
Number of subjects completed	20

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Protocol deviation: 4

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1

Arm description:

PEG-IFN and weight-based ribavirin (RBV): 24 weeks in those achieving rapid virologic response (RVR (>2 log drop within 100 days of infection)) (undetectable HCV RNA at 4 weeks) or 48 weeks in those not achieving RVR

Arm type	Active comparator
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	J05AB04
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1000 – 1200 mg daily (body mass-dependent) in two divided doses, to be taken orally

Investigational medicinal product name	PEG-IFN
Investigational medicinal product code	L03AB11
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180mcg once weekly

Arm title	Arm 2

Arm description:

PEG-IFN and weight-based RBV plus telaprevir (TPV): 12 weeks in those achieving RVR, 24 weeks in

those not achieving RVR (HCV RNA >25 but <1000 iU/mL at week 4) or 48 weeks in those not achieving RVR (HCV RNA >1000 iU/mL at week 4) Patients achieving HCV RNA <25 iU/mL at week 4 (RVR) were treated for 12 weeks. Patients with HCV RNA above 25 but below 1000 iU/mL at week 4 were treated for 24 weeks (12 weeks of TPV/Peg-IFN/RBV followed by 12 weeks of Peg-IFN/RBV). Patients in arm 2 with HCV RNA > 1000 iU/mL at week 4 discontinued Telaprevir, continuing with PEG-IFN/RBV for an additional 44 weeks beyond week 4.

Arm type	Experimental
Investigational medicinal product name	PEG-IFN
Investigational medicinal product code	L03AB11
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180mcg once weekly

Investigational medicinal product name	telaprevir
Investigational medicinal product code	J05AE11
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

2x 375mg tablets q8hrly or 3x375mg tablets BID

Investigational medicinal product name	Ribavirin
Investigational medicinal product code	J05AB04
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1000 – 1200 mg daily (body mass-dependent) in two divided doses, to be taken orally

Number of subjects in period 1[1]	Arm 1	Arm 2
Started	10	10
Completed	10	9
Not completed	0	1
Lost to follow-up	-	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 4 subjects failed the screening period and so were not included in the baseline period

Baseline characteristics

Reporting groups	
Reporting group title	Arm 1
Reporting group description:	
PEG-IFN and weight-based ribavirin (RBV): 24 weeks in those achieving rapid virologic response (RVR (>2 log drop within 100 days of infection)) (undetectable HCV RNA at 4 weeks) or 48 weeks in those not achieving RVR	
Reporting group title	Arm 2
Reporting group description:	
PEG-IFN and weight-based RBV plus telaprevir (TPV): 12 weeks in those achieving RVR, 24 weeks in those not achieving RVR (HCV RNA >25 but <1000 iU/mL at week 4) or 48 weeks in those not achieving RVR (HCV RNA >1000 iU/mL at week 4) Patients achieving HCV RNA <25 iU/mL at week 4 (RVR) were treated for 12 weeks. Patients with HCV RNA above 25 but below 1000 iU/mL at week 4 were treated for 24 weeks (12 weeks of TPV/Peg-IFN/RBV followed by 12 weeks of Peg-IFN/RBV). Patients in arm 2 with HCV RNA > 1000 iU/mL at week 4 discontinued Telaprevir, continuing with PEG-IFN/RBV for an additional 44 weeks beyond week 4.	

Reporting group values	Arm 1	Arm 2	Total
Number of subjects	10	10	20
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)	10	10	20
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
median	38.7	39.2	
full range (min-max)	26.9 to 58.7	31.6 to 49.7	-
Gender categorical Units: Subjects			
Female	0	0	0
Male	10	10	20
Self Described Ethnicity Units: Subjects			
English/Welsh/Scottish/Northern Irish/British	3	3	6
Irish	1	1	2
Any other white background	4	5	9
Chinese	1	0	1
African	0	1	1
Caribbean	1	0	1

End points

End points reporting groups

Reporting group title	Arm 1

Reporting group description:

PEG-IFN and weight-based ribavirin (RBV): 24 weeks in those achieving rapid virologic response (RVR (>2 log drop within 100 days of infection)) (undetectable HCV RNA at 4 weeks) or 48 weeks in those not achieving RVR

Reporting group title	Arm 2

Reporting group description:

PEG-IFN and weight-based RBV plus telaprevir (TPV): 12 weeks in those achieving RVR, 24 weeks in those not achieving RVR (HCV RNA >25 but <1000 iU/mL at week 4) or 48 weeks in those not achieving RVR (HCV RNA >1000 iU/mL at week 4) Patients achieving HCV RNA <25 iU/mL at week 4 (RVR) were treated for 12 weeks. Patients with HCV RNA above 25 but below 1000 iU/mL at week 4 were treated for 24 weeks (12 weeks of TPV/Peg-IFN/RBV followed by 12 weeks of Peg-IFN/RBV). Patients in arm 2 with HCV RNA > 1000 iU/mL at week 4 discontinued Telaprevir, continuing with PEG-IFN/RBV for an additional 44 weeks beyond week 4.

Primary: Comparison of rates of sustained virologic response (SVR24) between treatment arms; defined as HCV RNA not detectable at 24 weeks after planned completion of therapy.

End point title	Comparison of rates of sustained virologic response (SVR24) between treatment arms; defined as HCV RNA not detectable at 24 weeks after planned completion of therapy.[1]

End point description:

Comparison of SVR between arms by intention to treat analysis. Last observation HepC PCR <1000 iU/mL carried forward if data unavailable at a visit day. Where success is defined as any patient who achieves HepC PCR <1000 iU/mLn at a study visit time point and these results are assumed and retained for subsequent visits

End point type	Primary

End point timeframe:

24 weeks after planned completion of therapy.

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: Descriptive statistics only performed

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Subjects				
<1000 iU/mL	9	10		
>1000 iU/mL	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Comparison of proportion of treated patients achieving sustained virological response after 12 weeks of therapy (SVR12) between treatment arms;

defined as HCV RNA not detected at 12 weeks after planned completion of therapy	
End point title	Comparison of proportion of treated patients achieving sustained virological response after 12 weeks of therapy (SVR12) between treatment arms; defined as HCV RNA not detected at 12 weeks after planned completion of therapy

End point description:

Comparison of the parameters between arms by intention to treat analysis. . Last observation HepC PCR <1000 iU/mL carried forward if data unavailable at a visit day. Where success is defined as any patient who achieves HepC PCR <1000 iU/mL at a study visit time point and these results are assumed and retained for subsequent visits

End point type	Secondary

End point timeframe:

12 weeks after planned completion of therapy

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Subjects				
<1000 iU/mL	9	10		
>1000 iU/mL	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Comparison of proportion of treated patients with HCV RNA not detected at the planned end of treatment (EOT) between treatment arms	
End point title	Comparison of proportion of treated patients with HCV RNA not detected at the planned end of treatment (EOT) between treatment arms

End point description:

Comparison of the parameters between arms by intention to treat analysis.

End point type	Secondary

End point timeframe:

Baselines to 48 weeks

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: # Subjects with HCV RNA PCR <1000 iU/mL				
Baseline	0	1		
12 weeks	9	10		
24 weeks	9	10		
48 weeks	9	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Comparison of reduction in HCV RNA from baseline to week 4 between treatment arms

End point title	Comparison of reduction in HCV RNA from baseline to week 4 between treatment arms

End point description:

Comparison of the parameters between arms by intention to treat analysis.

End point type	Secondary

End point timeframe:

Baseline to week 4

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: # Subjects with HCV RNA PCR <1000 iU/mL				
Baseline	0	1		
Week 4	4	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Comparison of change in CD4 cell count between baseline and EOT between treatment arms

End point title	Comparison of change in CD4 cell count between baseline and EOT between treatment arms

End point description:

Comparison of the parameters between arms by intention to treat analysis.

End point type	Secondary

End point timeframe:

Baseline to End of Treatment

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: CD4 %				
median (inter-quartile range (Q1-Q3))				
Post Week 4	36.85 (27.80 to 41.50)	42.35 (38.65 to 43.60)		
Post Week 12	33.25 (31.10 to 36.20)	37.40 (36.20 to 39.30)		
Post week 24	36.75 (30.6 to 39.6)	34.90 (32.05 to 40.65)		

Statistical analyses

No statistical analyses for this end point

Secondary: Summary comparison of adverse events of grade III / IV intensity between treatment arms

End point title	Summary comparison of adverse events of grade III / IV intensity between treatment arms

End point description:

Comparison of the parameters between arms by intention to treat analysis.

End point type	Secondary

End point timeframe:

Adverse events were captured from the point of consent to the end of study participation for each subject

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Subjects				
Baseline	1	0		
Week 24	1	1		
Week 36	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Adherence to medication (as measured by adherence questioning and pill counts)

End point title	Adherence to medication (as measured by adherence questioning and pill counts)

End point description:

Comparison of the parameter between arms by intention to treat analysis

End point type	Secondary

End point timeframe:

Compliance was measured during the treatment phases of the study

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: # Non Compliant Subjects				
Week 2	0	1		
Week 4	3	1		
Week 8	2	1		
Week 12	1	2		
Week 24	1	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From consent to Last visit for each patient	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups	
Reporting group title	Arm 1
Reporting group description: -	
Reporting group title	Arm 2
Reporting group description: -	

Serious adverse events	Arm 1	Arm 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Gastrointestinal disorders			
RUPTURED COLON			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Arm 1	Arm 2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	10 / 10 (100.00%)	
Surgical and medical procedures			
Dental Extraction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Fatigue			

subjects affected / exposed	9 / 10 (90.00%)	7 / 10 (70.00%)	
occurrences (all)	9	7	
Febrile illness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Flu like illness			
subjects affected / exposed	0 / 10 (0.00%)	3 / 10 (30.00%)	
occurrences (all)	0	3	
Flu like symptoms			
subjects affected / exposed	3 / 10 (30.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
Lethargy			
subjects affected / exposed	0 / 10 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
Loss of appetite			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Low appetite			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Shiver			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Tiredness			
subjects affected / exposed	0 / 10 (0.00%)	3 / 10 (30.00%)	
occurrences (all)	0	3	
Tiredness / 1 episode of synope			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Immune system disorders			

Cough			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Dry Skin			
subjects affected / exposed	1 / 10 (10.00%)	2 / 10 (20.00%)	
occurrences (all)	1	2	
Hayfever			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Sore Throat			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
Erectile Dysfunction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
SUPERFICIAL THROMBOPHLEBITIS (DORSAL PENILE VEINS)			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Viral URTI			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
EPITAXIS			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Left side chest discomfort			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Shortness of breath on exertion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	4 / 10 (40.00%)	
occurrences (all)	0	4	
LOW MOOD			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Mood swings			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Sleep disturbances			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Worsening anxiety			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Worsening Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 10 (20.00%)	2 / 10 (20.00%)	
occurrences (all)	2	2	
Lack of concentration			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
low hemoglobin			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Acute gastroenteritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

Anaemia				
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
COLOSTOMY				
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
Diarrhoea				
subjects affected / exposed	2 / 10 (20.00%)	4 / 10 (40.00%)		
occurrences (all)	2	4		
Diffuse itchiness				
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
Doxycycline related nausea				
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
Dry Cough				
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
E. Coli UTI				
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
Early Satiety				
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
Frequency stool				
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
Gastroenteritis acute				
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
Heartburn				
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)		
occurrences (all)	1	1		
Loose stool				
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)		
occurrences (all)	2	1		

Nausea			
subjects affected / exposed	0 / 10 (0.00%)	4 / 10 (40.00%)	
occurrences (all)	0	4	
Oesophageal reflux			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Post surgical bowel occlusion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Shigellosis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Soft stool			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Stomach Cramp			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Aplithris mouth ulcer			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Arthralgia knee			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Dermatitis oricomieosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Dry thickened skin both ankles			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Itch			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Itchy rash			

subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Itchy skin			
subjects affected / exposed	0 / 10 (0.00%)	3 / 10 (30.00%)	
occurrences (all)	0	3	
Middle finger L. hand itching swelling			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Mosquito bites			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Mouth ulcer			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Night sweats			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Oral candidiasis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Pruritis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Red spot on face			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
SKIN SCALP INFECTION			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Skin tag removal			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Wasp sting			

subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Worsening proteinuria (renoprotective)			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Aches and pains			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Acne/Back + neck			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Bone aches Pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Left hip burisitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Left upper arm bruise. Mechanical fall			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Mild discomfort right flank			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

Myalgia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
right 3RD metacarphalagial joint pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Right knee pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Infections and infestations			
Anal Gonorhoea			
subjects affected / exposed	3 / 10 (30.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
Angular cheilitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Anxiety (worsening)			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Chlamydia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Dental Abscess			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Dental infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Herpatic lip ulcer			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Onychomycose left toe nail			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Peritonitis			

subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Secondary syphilis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Syphilis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 October 2013	This amendment was generated in order to clarify points raised by the ethics committee in their letter dated 16th July 2013, and to add that viral load plasma samples will be stored for possible further testing.
07 January 2014	Addition of fibroscans, clarify the study follow up visits, remove the hepatitis C risk factors questionnaire, increase the volume of blood taken for stored samples and update the dosing information, as well as to make a number of administrative changes.
01 September 2014	Updated in line with new safety information from Pegasys® SPC. Addition of glucose testing and Hep-B Testing. Updated contraception advice
26 November 2015	Data to be combined with that from a similar study (An open label, randomised, non-inferiority trial of pegylated interferon, ribavirin and telaprevir versus pegylated interferon and ribavirin alone in the response guided treatment of acute hepatitis C genotype 1 virus infection in patients with HIV-1 co-infection (CHAT Study)) which was being concurrently carried out by the University of Bonn, Germany. The PIs from the 2 studies were to lead the combined analysis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported