Clinical trial results:
A phase IV open-label multicentre, international trial of response guided treatment with directly observed pegylated interferon alfa 2b and self-administered ribavirin for patients with chronic HCV genotype 2 or 3 infection and ongoing injection drug use.

Summary

EudraCT number	2010-024557-36
Trial protocol	GB BE DE
Global end of trial date	20 October 2015

Results information

Result version number	v1 (current)
This version publication date	16 October 2019
First version publication date	16 October 2019
Summary attachment (see zip file)	Primary paper ACTIVATE study 2017 (Grebely Int J of Drug Pol 2017.pdf)

Trial information

Trial identification

Sponsor protocol code	VHCRP1007

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01364090
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of New South Wales, The Kirby Institute
Sponsor organisation address	Wallace Wurth building, Sydney, Australia, 2052 NSW
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Scientific contact	Professor Gregory Dore, University of New South Wales, The Kirby Institute, +61 0293850898, gdore@kirby.unsw.edu.au

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	20 October 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the proportion of patients with undetectable HCV RNA at 12 weeks post end of treatment (SVR12) following directly observed PEG-IFN alfa-2b (1.5 µg/kg weekly, to a maximum of 150 µg/week) in combination with self-administered ribavirin (800-1400 milligrams daily) for 12 weeks in participants with non-quantifiable (<15 IU/ml detected and <15 IU/ml undetected) HCV RNA or undetectable HCV RNA on qualitative assay at week 4 of therapy, and for 24 weeks in participants with quantifiable (≥15 IU/ml) HCV RNA or detectable HCV RNA on qualitative assay at week 4 of therapy. In this feasibility study, the primary endpoint measurement of efficacy of treatment will be SVR12.

Protection of trial subjects:

Not applicable

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 September 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	30 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 40
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Switzerland: 9
Country: Number of subjects enrolled	Norway: 12
Country: Number of subjects enrolled	United Kingdom: 7
Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Germany: 4
Worldwide total number of subjects	93
EEA total number of subjects	29

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)	93
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From May 11, 2012, to September 30, 2014, participants were enrolled at 17 sites in Australia (n = 5), Belgium (n = 2), Canada (n = 3), Germany (n = 1), Norway (n = 2), Switzerland (n = 3) and the United Kingdom (n = 1). The last participant visit was July 15, 2015.

Pre-assignment

Screening details:

Participants had to be >18 years of age, have chronic HCV genotype 2 or 3 infection, be HCV treatment-naïve, and have reported recent injecting drug use. 119 patients were screened and 93 were enrolled. Among the 26 patients who were excluded, 7 refused to participate, 11 were ineligible and 8 were excluded for other reasons

Period 1

Period 1 title	baseline
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	all subjects

Arm description: -

Arm type	baseline
Investigational medicinal product name	PEG-IFN & Ribavirin
Investigational medicinal product code	PEF-IFN, RBV
Other name	
Pharmaceutical forms	Tablet, Suspension for suspension for injection
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

pegylated interferon alfa-2b (PEG-IFN weekly, 1.5 mg/kg/week) and self-administered ribavirin (RBV, 800–1400 mg daily, weight-based)

Number of subjects in period 1	all subjects
Started	93
Completed	93

Period 2

Period 2 title	Completed trial
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Shortened therapy

Arm description:

Participants with an RVR [defined as non-quantifiable HCV RNA (<15 IU/ml detected and <15 IU/ml undetected) or undetectable HCV RNA on qualitative assay at week 4] received 12 weeks of therapy (shortened duration).

Arm type	Experimental
Investigational medicinal product name	PEG-IFN & Ribavirin
Investigational medicinal product code	PEF-IFN, RBV
Other name	
Pharmaceutical forms	Tablet, Suspension for suspension for injection
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

pegylated interferon alfa-2b (PEG-IFN weekly, 1.5 mg/kg/week) and self-administered ribavirin (RBV, 800–1400 mg daily, weight-based)

Arm title	Standard therapy

Arm description:

Participants without an RVR [defined as quantifiable HCV RNA (15 IU/ml) or detectable HCV RNA on qualitative assay at week 4] received 24 weeks of therapy (standard duration).

Arm type	Standard arm
Investigational medicinal product name	PEG-IFN & Ribavirin
Investigational medicinal product code	PEF-IFN, RBV
Other name	
Pharmaceutical forms	Suspension for suspension for injection, Tablet
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

pegylated interferon alfa-2b (PEG-IFN weekly, 1.5 mg/kg/week) and self-administered ribavirin (RBV, 800–1400 mg daily, weight-based)

Number of subjects in period 2[1]	Shortened therapy	Standard therapy
Started	61	26
Week 4	61	26
ETR	59	12
SVR12	51	10
Completed	51	10
Not completed	10	16
Medical contraindication	1	2
Consent withdrawn by subject	2	3
Relapse	3	2
Adverse event, non-fatal	1	4
Lost to follow-up	3	4
Lack of efficacy	-	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The period 2 starts at Week 4 where subjects are allocated to an arm (standard or shortened therapy). 4 subjects withdrew (for various reasons) the study between baseline (period 1) and the start of period 2 (starting at Week 4).

Baseline characteristics

Reporting groups	
Reporting group title	baseline

Reporting group description: -

Reporting group values	baseline	Total	
Number of subjects	93	93	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Adults <64		0	
Age continuous			
Age was captured in the electronic case report form for all 93 enrolled participants.			
Units: years			
median	41		
inter-quartile range (Q1-Q3)	35 to 49	-	
Gender categorical			
Gender was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
Female	16	16	
Male	77	77	
Not recorded	0	0	
Ethnicity			
Ethnicity was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
Caucasian	84	84	
Non caucasian	9	9	
Not recorded	0	0	
Education			
Education was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
High school or higher education	40	40	
No high school or higher education	53	53	
Not recorded	0	0	
Housing			
Housing was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
Stable housing	71	71	

Non stable housing	22	22	
Not recorded	0	0	
Imprisonment			
Imprisonment was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
History of imprisonment	66	66	
No history of imprisonment	27	27	
Not recorded	0	0	
Drug use in the last 6 months			
Drug use in the last 6 months was captured in the case report form for all 93 participants.			
Units: Subjects			
injecting	77	77	
non-injecting	16	16	
Not recorded	0	0	
Drug use in the last month			
Drug use in the last month was captured in the case report form for all 93 participants.			
Units: Subjects			
injecting	62	62	
non-injecting	31	31	
Not recorded	0	0	
History of any injecting drug use (IDU)			
History of any injecting drug use was captured in the case report form for all 93 participants.			
Units: Subjects			
History of IDU	89	89	
No history of IDU	4	4	
Not recorded	0	0	
Injecting drug use frequency in the last month			
Injecting drug use frequency in the last month was captured in the case report form for all 93 participants.			
Units: Subjects			
Never	38	38	
> daily	15	15	
< daily	40	40	
Not recorded	0	0	
Opioid substitution treatment (OST)			
Opioid substitution treatment was captured in the case report form for all 93 participants.			
Units: Subjects			
OST ever	82	82	
No history of OST	11	11	
Not recorded	0	0	
HCV genotype			
HCV genotype was captured in the case report form for all 93 participants.			
Units: Subjects			
1a	1	1	
2b	7	7	
2a	2	2	
3a	83	83	
Not recorded	0	0	
Stage of liver disease			
Stage of liver disease was captured in the case report form for all 93 participants.			
Units: Subjects			

No or mild fibrosis (F0-F1)	63	63	
Moderate or advanced fibrosis (F2-F3)	20	20	
Cirrhosis (F4)	10	10	
Not recorded	0	0	
Mean BMI			
Mean BMI was captured in the electronic case report form for all 93 enrolled participants.			
Units: kg/m2			
median			
standard deviation	±	-	
Age of first injecting drug use			
History of any injecting drug use was captured in the case report form for 92 participants (1 missing value).			
Units: years			
median			
inter-quartile range (Q1-Q3)		-	
Mean HCV RNA			
Mean HCV RNA was captured in the case report form for all 93 participants.			
Units: log IU/mL			
median			
inter-quartile range (Q1-Q3)		-	

Subject analysis sets

Subject analysis set title	ITT analysis
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All subjects who have received at least one dose of PEG-IFN

Reporting group values	ITT analysis		
Number of subjects	93		
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Adults <64			
Age continuous			
Age was captured in the electronic case report form for all 93 enrolled participants.			
Units: years			
median	41		
inter-quartile range (Q1-Q3)	35 to 49		

Gender categorical			
Gender was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
Female	16		
Male	77		
Not recorded	0		
Ethnicity			
Ethnicity was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
Caucasian	84		
Non caucasian	9		
Not recorded	0		
Education			
Education was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
High school or higher education	40		
No high school or higher education	53		
Not recorded	0		
Housing			
Housing was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
Stable housing	71		
Non stable housing	22		
Not recorded	0		
Imprisonment			
Imprisonment was captured in the electronic case report form for all 93 enrolled participants.			
Units: Subjects			
History of imprisonment	66		
No history of imprisonment	27		
Not recorded	0		
Drug use in the last 6 months			
Drug use in the last 6 months was captured in the case report form for all 93 participants.			
Units: Subjects			
injecting	77		
non-injecting	16		
Not recorded	0		
Drug use in the last month			
Drug use in the last month was captured in the case report form for all 93 participants.			
Units: Subjects			
injecting	62		
non-injecting	31		
Not recorded	0		
History of any injecting drug use (IDU)			
History of any injecting drug use was captured in the case report form for all 93 participants.			
Units: Subjects			
History of IDU	89		
No history of IDU	4		
Not recorded	0		
Injecting drug use frequency in the last month			
Injecting drug use frequency in the last month was captured in the case report form for all 93 participants.			

Units: Subjects			
Never	38		
> daily	15		
< daily	40		
Not recorded	0		
Opioid substitution treatment (OST)			
Opioid substitution treatment was captured in the case report form for all 93 participants.			
Units: Subjects			
OST ever	82		
No history of OST	11		
Not recorded	0		
HCV genotype			
HCV genotype was captured in the case report form for all 93 participants.			
Units: Subjects			
1a	1		
2b	7		
2a	2		
3a	83		
Not recorded	0		
Stage of liver disease			
Stage of liver disease was captured in the case report form for all 93 participants.			
Units: Subjects			
No or mild fibrosis (F0-F1)	63		
Moderate or advanced fibrosis (F2-F3)	20		
Cirrhosis (F4)	10		
Not recorded	0		
Mean BMI			
Mean BMI was captured in the electronic case report form for all 93 enrolled participants.			
Units: kg/m2			
median	26		
standard deviation	± 5.4		
Age of first injecting drug use			
History of any injecting drug use was captured in the case report form for 92 participants (1 missing value).			
Units: years			
median	20		
inter-quartile range (Q1-Q3)	16 to 26		
Mean HCV RNA			
Mean HCV RNA was captured in the case report form for all 93 participants.			
Units: log IU/mL			
median	6.08		
inter-quartile range (Q1-Q3)	5.63 to 6.70		

End points

End points reporting groups

Reporting group title	all subjects
Reporting group description: -	
Reporting group title	Shortened therapy
Reporting group description:	
Participants with an RVR [defined as non-quantifiable HCV RNA (<15 IU/ml detected and <15 IU/ml undetected) or undetectable HCV RNA on qualitative assay at week 4] received 12 weeks of therapy (shortened duration).	
Reporting group title	Standard therapy
Reporting group description:	
Participants without an RVR [defined as quantifiable HCV RNA (15 IU/ml) or detectable HCV RNA on qualitative assay at week 4] received 24 weeks of therapy (standard duration).	
Subject analysis set title	ITT analysis
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All subjects who have received at least one dose of PEG-IFN	

Primary: Sustained virologic response at 12 weeks post-treatment (SVR12)

End point title	Sustained virologic response at 12 weeks post-treatment (SVR12)
End point description:	
The aim of this endpoint was to compare the percentage of patients with an SVR among those who receive HCV therapy for 12 weeks (non-quantifiable HCV RNA [i.e. <15 IU/ml detected and <15 IU/ml undetected] or undetectable HCV RNA on qualitative assay at week 4) and 24 weeks (quantifiable HCV RNA [i.e. ≥15 IU/ml] or detectable HCV RNA on qualitative assay at week 4)	
End point type	Primary
End point timeframe:	
HCV RNA results were collected 12 weeks after the end of treatment of study participants.	

End point values	Shortened therapy	Standard therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	26		
Units: subjects				
number (not applicable)				
HCV RNA undetectable	51	10		

Statistical analyses

Statistical analysis title	Primary endpoint
Statistical analysis description:	
A total of 100 subjects is planned for enrolment and evaluation as the intention-to-treat population. This study population was chosen to provide a reasonably precise measure of treatment response and evaluate the feasibility of recruitment of active IDUs through the multinational network. Assuming an overall SVR of 70%, the 95% confidence intervals around this estimate will be 60% to 79%.	
Comparison groups	Shortened therapy v Standard therapy

Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
lower limit	60
upper limit	79

Secondary: End of treatment (ETR)

End point title	End of treatment (ETR)

End point description:

The aim of this endpoint was to compare the percentage of patients with ETR among those who receive HCV therapy for 12 weeks (non-quantifiable HCV RNA [i.e. <15 IU/ml detected and <15 IU/ml undetected] or undetectable HCV RNA on qualitative assay at week 4) and 24 weeks (quantifiable HCV RNA [i.e. ≥15 IU/ml] or detectable HCV RNA on qualitative assay at week 4)

End point type	Secondary

End point timeframe:

HCV RNA results were collected at the end of treatment of study participants (either 12 or 24 weeks depending on the arm of treatment).

End point values	Shortened therapy	Standard therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	26		
Units: Subjects				
number (not applicable)				
HCV RNA undetectable at ETR	58	12		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: All subjects were monitored for the occurrence of Adverse Events from screening through to 24 weeks following cessation of therapy.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Reporting groups	
Reporting group title	Overall
Reporting group description: All patients enrolled in the study	
Reporting group title	Standard therapy
Reporting group description: Subjects in the standard therapy arm	
Reporting group title	Shortened therapy
Reporting group description: Subjects in the shortened therapy arm	

Serious adverse events	Overall	Standard therapy	Shortened therapy
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 93 (11.83%)	4 / 26 (15.38%)	6 / 61 (9.84%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Pseudo-aneurysm			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Non-sustained ventricular tachycardia			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Accident automobile			

subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Nausea and vomiting			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emesis			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small bowel obstruction			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Abscess			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	1 / 93 (1.08%)	1 / 26 (3.85%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dependance			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Drug intoxication			

subjects affected / exposed	3 / 93 (3.23%)	1 / 26 (3.85%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Unspecified drug dependence			
subjects affected / exposed	1 / 93 (1.08%)	0 / 26 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug overdose			
subjects affected / exposed	3 / 93 (3.23%)	1 / 26 (3.85%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 93 (1.08%)	1 / 26 (3.85%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Overall	Standard therapy	Shortened therapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 93 (97.85%)	26 / 26 (100.00%)	60 / 61 (98.36%)
Injury, poisoning and procedural complications			
Injection site erythema			
subjects affected / exposed	17 / 93 (18.28%)	4 / 26 (15.38%)	8 / 61 (13.11%)
occurrences (all)	17	4	8
Nervous system disorders			
Headache			
subjects affected / exposed	35 / 93 (37.63%)	14 / 26 (53.85%)	21 / 61 (34.43%)
occurrences (all)	35	14	21
Insomnia			
subjects affected / exposed	19 / 93 (20.43%)	4 / 26 (15.38%)	15 / 61 (24.59%)
occurrences (all)	19	4	15
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	48 / 93 (51.61%)	14 / 26 (53.85%)	33 / 61 (54.10%)
occurrences (all)	48	14	33
Influenza like illness			
subjects affected / exposed	36 / 93 (38.71%)	13 / 26 (50.00%)	19 / 61 (31.15%)
occurrences (all)	36	13	19
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	17 / 93 (18.28%)	5 / 26 (19.23%)	12 / 61 (19.67%)
occurrences (all)	17	5	12
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	33 / 93 (35.48%)	5 / 26 (19.23%)	26 / 61 (42.62%)
occurrences (all)	33	5	26
Vomiting			
subjects affected / exposed	18 / 93 (19.35%)	5 / 26 (19.23%)	11 / 61 (18.03%)
occurrences (all)	18	5	11
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	17 / 93 (18.28%)	5 / 26 (19.23%)	12 / 61 (19.67%)
occurrences (all)	17	5	12
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	26 / 93 (27.96%)	7 / 26 (26.92%)	18 / 61 (29.51%)
occurrences (all)	26	7	18
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	25 / 93 (26.88%)	6 / 26 (23.08%)	19 / 61 (31.15%)
occurrences (all)	25	6	19

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 June 2013	Protocol amended to v5 dated 24-Jun-13. Changes were: - inclusion of patients receiving opiates substitution therapy - primary variable to assess efficacy changed to SVR12 - definition of active injecting drug use changed to 24 weeks prior to consent - definitions of detectable and undetectable HCV RNA clarified - PEG-IFN administration: Week 6 visit inserted
09 December 2014	Protocol v5 updated to protocol v6 dated 9-Dec-14. Changes were: - Addition of a follow-up 1 visit (long term follow-up) from 24 to 132 weeks post-treatment

Notes:

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 population may not be generalizable to all populations of PWID and may reflect a population more engaged in health services.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28624134