Clinical trial results:
A phase III open label study to evaluate safety and efficacy of Boceprevir-response guided therapy in controlled HIV patients with chronic hepatitis C genotype 1 infection who failed previously to Peginterferon /ribavirin.

Summary

EudraCT number	2012-003984-23
Trial protocol	ES
Global end of trial date	30 June 2015

Results information

Result version number	v1 (current)
This version publication date	27 August 2025
First version publication date	27 August 2025

Trial information

Trial identification

Sponsor protocol code	BOC-HIV

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01718301
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Clínic per a la Recerca Biomèdica
Sponsor organisation address	C/ Rossello 143, Barcelona, Spain,
Public contact	CTU Clinic, CTU clinic (Clinical Trial Unit). Farmacología Clínica. hospital clinic, +34 9322754009838, mallolas@clinic.ub.es
Scientific contact	CTU Clinic, CTU clinic (Clinical Trial Unit). Farmacología Clínica. hospital clinic, +34 9322754009838, mallolas@clinic.ub.es

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	30 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 March 2015
Global end of trial reached?	Yes
Global end of trial date	30 June 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the safety and efficacy of a Response Guided Therapy of boceprevir 800 mg dosed TID orally (PO) in combination with Peginterferon (either alpha 2b or alpha 2a) and Ribavirin in HIV/HCV genotype 1 infected patients that failed to previous HCV therapy .

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki and Spanish legislation (Royal Decree 223/2004). Ethics Committee and regulatory approvals were obtained prior to initiation. Informed consent was provided in writing and orally, and patient confidentiality was ensured following data protection laws. A liability insurance policy was in place.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 February 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	Spain: 102
Worldwide total number of subjects	102
EEA total number of subjects	102

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)	102
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening included informed consent, eligibility check, medical history, physical exam, vital signs, lab tests (HCV RNA, CD4, HIV VL), and imaging (Fibroscan or biopsy, ultrasound for cirrhotics) to confirm genotype 1 and stable HIV infection.

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	Boceprevir + Ribavirin + Peginterferon

Arm description:

Participants received 4 weeks of Peginterferon/Ribavirin (lead-in), followed by response-guided therapy with
Boceprevir added. Cirrhotic patients received a fixed 44-week regimen.
Boceprevir 800 mg three times a day (v.o.) in combination with Peginterferon (alfa-2b or alfa-2a) and Ribavirin

Arm type	Experimental
Investigational medicinal product name	Boceprevir
Investigational medicinal product code	
Other name	Victrelis®, BOC
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Boceprevir (BOC) 800 mg (4 capsules) three times a day . Total 2400 mg/day (12 capsules).
Boceprevir is administered three times a day using a dosing schedule of 4 capsules every 8 hours

Investigational medicinal product name	Peginterferon (alpha-2b or alpha-2a)
Investigational medicinal product code	
Other name	Pegasys® (alfa-2a) o Pegintron® (alfa-2b)
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Peginterferon alfa-2b: 80-150mcg or peginterferon alfa-2a: 180 micrograms
Injectable solution, administered subcutaneously once weekly.

Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Ribavirin Teva®
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

ribavirin: 200 mg capsules, administered orally, dose adjusted by weight.

Number of subjects in period 1[1]	Boceprevir + Ribavirin + Peginterferon
Started	98
Completed	76
Not completed	22
Adverse event, serious fatal	1
Consent withdrawn by subject	2
Physician decision	12
Adverse event, non-fatal	6
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: Four subjects were enrolled but did not start treatment due to screening failure (2) or early withdrawal before first dose administration (2).

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	98	98	
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	
Age continuous Units: years			
arithmetic mean	49		
standard deviation	± 6	-	
Gender categorical Units: Subjects			
Female	26	26	
Male	72	72	

End points

End points reporting groups

Reporting group title	Boceprevir + Ribavirin + Peginterferon

Reporting group description:

Participants received 4 weeks of Peginterferon/Ribavirin (lead-in), followed by response-guided therapy with
Boceprevir added. Cirrhotic patients received a fixed 44-week regimen.
Boceprevir 800 mg three times a day (v.o.) in combination with Peginterferon (alfa-2b or alfa-2a) and Ribavirin

Primary: Achievement of Sustained Virological Response (SVR) at 24 Weeks Post-Treatment

End point title	Achievement of Sustained Virological Response (SVR) at 24 Weeks Post-Treatment[1]

End point description:

Achievement of SVR, defined as undetectable plasma HCV-RNA at Follow-up Week (FW) 24.
If a subject is missing FW 24 data and has undetectable HCV-RNA level at FW 12, the subject would be considered an SVR.

End point type	Primary

End point timeframe:

Week 24

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: The primary endpoint was assessed using descriptive statistics only. No formal statistical comparison was planned due to the single-arm design of the study.

End point values	Boceprevir + Ribavirin + Peginterferon			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: Subjects				
Number of participants achieving SVR	66			
Number of participants not achieving SVR 32	32			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From informed consent until 30 days after study completion or discontinuation.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	Boceprevir + Ribavirin + Peginterferon

Reporting group description: -

Serious adverse events	Boceprevir + Ribavirin + Peginterferon		
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 98 (19.39%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Blood and lymphatic system disorders			
Thrombocytopenia, neutropenia, anemia			
subjects affected / exposed	16 / 98 (16.33%)		
occurrences causally related to treatment / all	16 / 16		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Other SAEs			
subjects affected / exposed	2 / 98 (2.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Boceprevir + Ribavirin + Peginterferon		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 98 (92.86%)		
General disorders and administration site conditions			
Other	Additional description: Most AEs were mild and known to be related to PEG-IFN/RBV and BOC therapy (flu-like symptoms, asthenia, neuropsychiatric symptoms, hematological toxicity, dysgeusia, and rash).		
subjects affected / exposed	91 / 98 (92.86%)		
occurrences (all)	633		

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 main limitation of this study is the absence of a control group.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27815225