Clinical trial results:
An Open-Label Study to Explore the Clinical Efficacy of Sofosbuvir With Ribavirin Administered Pre-Transplant in Preventing Hepatitis C Virus (HCV) Recurrence Post-Transplant in HIV-HCV infected patients

Summary

EudraCT number	2014-001739-35
Trial protocol	IT
Global end of trial date	20 February 2017

Results information

Result version number	v1 (current)
This version publication date	01 February 2020
First version publication date	01 February 2020

Trial information

Trial identification

Sponsor protocol code	SOFT-preOLT

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01559844
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Università di Modena e Reggio Emilia
Sponsor organisation address	via del Pozzo, 71, Modena, Italy,
Public contact	Researcher, Università di Modena e ReggioEmilia, +39 0594225318, giovanni.guaraldi@unimore.it
Scientific contact	Researcher, Università di Modena e ReggioEmilia, +39 0594225318, giovanni.guaraldi@unimore.it

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 May 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 February 2017
Global end of trial reached?	Yes
Global end of trial date	20 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine if the administration of a combination of sofosbuvir and ribavirin to HIV-HCV co-infected subjects prior to undergoing liver transplantation for up to 48 weeks (or the time of transplant) can prevent post-transplant HCV re-infection as determined by a sustained post-transplant virological response (HCV RNA <LLoQ) at 12 weeks post-transplant

Protection of trial subjects:

No particular actions

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2014
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	Italy: 11
Worldwide total number of subjects	11
EEA total number of subjects	11

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)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

recruitment period 6th Oct 2014-31st Oct-2016

Pre-assignment

Screening details:

All the screened subjects were enrolled in the trial. No screening-failure

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	Treatment

Arm description:

sofosbuvir (Sovaldi) and after the approved Amendment sofosbuvir+ledipasvir (Harvoni)

Arm type	Experimental
Investigational medicinal product name	sofosbuvir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

400mg QD

Investigational medicinal product name	Harvoni (sofosbuvir+ledipasvir)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

sofosbuvir + ledipasvir= 400 mg/90mg QD

Number of subjects in period 1	Treatment
Started	11
Completed	11

Baseline characteristics

Reporting groups	
Reporting group title	overall trial
Reporting group description:	
11	

Reporting group values	overall trial	Total	
Number of subjects	11	11	
Age categorical			
>18 years			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	11	11	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
adults			
Units: years			
median	51		
inter-quartile range (Q1-Q3)	50 to 52	-	
Gender categorical			
Units: Subjects			
Female	3	3	
Male	8	8	

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description:

sofosbuvir (Sovaldi) and after the approved Amendment sofosbuvir+ledipasvir (Harvoni)

Primary: sustained post-transplant virological response (HCV RNA <LLoQ)

End point title	sustained post-transplant virological response (HCV RNA <LLoQ)[1]

End point description:

End point type	Primary

End point timeframe:

12 week post orthotopic liver transplant

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: Only descriptive analysis was perfomed. Only one arm.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: copies/ml				
number (not applicable)	11			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: from consent form signature to last patient last visit	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Considering the particularly complex conditions of patients in waiting list for orthotopic liver transplantation, all reported clinical conditions are considered pre-existing and related to the underlying pathology.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 February 2015	Based on international guidelines replacement of sofosbuvir with sofosbuvir+ledipasvir

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported