Clinical trial results:
Two treatment strategies with Ribavirin for Chronic Hepatitis E and severe acute forms randomized study

Summary

EudraCT number	2015-000699-91
Trial protocol	ES
Global end of trial date	07 November 2018

Results information

Result version number	v1 (current)
This version publication date	30 January 2022
First version publication date	30 January 2022

Trial information

Trial identification

Sponsor protocol code	RACHE

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	VHIR
Sponsor organisation address	Passeig Vall Hebron 119-129, Barcelona, Spain, 08035
Public contact	Joaquin Lopez-Soriano, Fundación Hospital Vall Hebron Institut de Recerca, 0034 934894779, joaquin.lopez.soriano@vhir.org
Scientific contact	Servicio Hepatología, Fundación Hospital Vall Hebron Institut de Recerca, 0034 934893000, resteban@vhebron.net

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	07 November 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 November 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy assessment (sustained virologic response rate) with Ribavirin in two therapeutic strategies with ribavirin, in patients with chronic and severe acute hepatitis E.

Protection of trial subjects:

No specific measures were necessary

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2015
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: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	4
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at Vall Hebron Hospital (Barcelona, Spain)

Pre-assignment

Screening details:

Patients were selected form the CHES (Chronic Hepatitis E Screening) multicenter study including patients with immune impairment and increased transaminases levels. 381 patients in total were included in that study, from which patients were selected.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	12 weeks

Arm description:

12 weeks treatment with ribavarin

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

Dosage and administration details:

600mg daily dose for 12 weeks

Arm title	24 weeks

Arm description:

24 weeks treatment if RNA detectable at 4 weeks after starting treatment, or else treatment only 12 weeks if RNA undetectable at 4 weeks

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

Dosage and administration details:

600mg daily dose for: 12 weeks if RNA not detectable at week 4; or 24 weeks if RNA detectable at 4 weeks, adjusted to renal function

Number of subjects in period 1	12 weeks	24 weeks
Started	2	3
Completed	2	3

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	5	5	
Age categorical Units: Subjects			
Adults (18-64 years)	5	5	
Gender categorical Units: Subjects			
Female	1	1	
Male	4	4	

End points

End points reporting groups

Reporting group title	12 weeks

Reporting group description:

12 weeks treatment with ribavarin

Reporting group title	24 weeks

Reporting group description:

24 weeks treatment if RNA detectable at 4 weeks after starting treatment, or else treatment only 12 weeks if RNA undetectable at 4 weeks

Primary: RNA not detectable

End point title	RNA not detectable[1]

End point description:

Hepatatis E Virus RNA levels were assessed 48 weeks after ending of treatment

End point type	Primary

End point timeframe:

48 weeks after finishing treatment

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 small sample size makes impossible a statistical analysis

End point values	12 weeks	24 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	3		
Units: Patients				
number (not applicable)	1	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 48 weeks after tretament	
Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

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

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: None adverse events were reported in the study

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.

Small sample size makes desirable further studies with larger groups

Notes: