Clinical trial results:
A clinical study to evaluate the biological effects of administering rimantadine in patients with hepatitis C virus (HCV) infection alongside standard combination therapy with pegylated interferon and ribavirin.

Summary

EudraCT number	2011-002781-21
Trial protocol	GB
Global end of trial date	10 June 2014

Results information

Result version number	v1 (current)
This version publication date	27 February 2020
First version publication date	27 February 2020
Summary attachment (see zip file)	HepriaCT Final Report (9730_EndOfTrialSummaryReport_signed_150517.pdf)

Trial information

Trial identification

Sponsor protocol code	CO11/9730

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Leeds Teaching Hospitals NHS Trust
Sponsor organisation address	St James University hospital , Leeds, United Kingdom, LS9 7TF
Public contact	Lynsey Corless, Leeds Teaching Hospitals, 0775 3682468, lynsey.corless@nhs.net
Scientific contact	Lynsey Corless, Leeds Teaching Hospitals, 0775 3682468, lynsey.corless@nhs.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	10 June 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 June 2014
Global end of trial reached?	Yes
Global end of trial date	10 June 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary aim of the study is to determine whether rimantadine (a drug developed and used for the treatment of Influenza A infection) has antiviral effects on hepatitis C virus (HCV).

Protection of trial subjects:

All information collected during the course of the trial will be kept strictly confidential.Information will be held securely for the duration of the study.Patients with HCV attending the Hepatology clinic for assessment who meet the basic trial inclusion criteria will be given a verbal explanation of the trial. Those who express an interest in participating will be provided with a patient information sheet by a clinician. This will include detailed information about the rationale, design and personal implications of the study. Patients who do not have English as a first language will be offered a patient information sheet in their preferred language. Following information provision, patients will have at least 24 hours to consider participation and will be given the opportunity to discuss the trial with their family and healthcare professionals before they are asked whether they would be willing to take part in the trial. During the initial clinic visit, those who have expressed an interest in the trial will be asked to give permission for trial staff to contact them by phone to answer any remaining questions and to enquire if they wish to participate. This process will be clearly documented into the patient’s medical notes.Assenting patients will then be formally assessed for eligibility and invited to provide informed, written consent. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment. A copy of the consent will be given to the patient, one filed in the trial master file, one filed in the hospital notes and a fourth copy sent to the Sponsor.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 July 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	8
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients screened as per the recruitment criteria. Assenting patients will then be formally assessed for eligibility and invited to provide informed, written consent. The right of the patient to refuse consent without giving reasons will be respected.

Pre-assignment

Screening details:

Patients with HCV attending the Hepatology clinic for assessment who meet the basic trial inclusion criteria will be given a verbal explanation of the trial. Those who express an interest in participating will be provided with a patient information sheet by a clinician.This will include detailed information about the study.

Period 1

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

Blinding implementation details:

N/A

Arms

Are arms mutually exclusive?	Yes
Arm title	Baseline Arm

Arm description: -

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

Dosage and administration details:

Rimantadine hydrochloride is supplied in 50 mg film-coated tablets, intended for oral administration and tablets are stored at room temperature.
Rimantadine will be provided to the Chief Investigators in tablet form by the hospital pharmacy. Labels will indicate the product, lot number and dose.

Arm title	End Data

Arm description: -

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

Dosage and administration details:

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Number of subjects in period 1	Baseline Arm	End Data
Started	1	7
Completed	1	7

Baseline characteristics

Reporting groups	
Reporting group title	Main Trial Period

Reporting group description: -

Reporting group values	Main Trial Period	Total	
Number of subjects	8	8	
Age categorical 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)	8	8	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	8	8	

End points

End points reporting groups

Reporting group title	Baseline Arm
Reporting group description: -	
Reporting group title	End Data
Reporting group description: -	

Primary: Detection of genomic sequence alterations in patients receiving rimantadine.

End point title	Detection of genomic sequence alterations in patients receiving rimantadine.[1]

End point description:

The primary objective of the study is to determine whether the addition of rimantadine therapy leads to alterations in HCV genomic sequences. This would provide evidence that rimantadine exerts a true antiviral effect on HCV and could lead to larger trials, assessing whether rimantadine therapy had a statistically significant effect on treatment response. Improvements in treatment response will correlate with a reduction in the prevalence of chronic HCV infection and a consequent reduction in cases of liver failure and hepatocellular carcinoma.

End point type	Primary

End point timeframe:

Patients exposed to treatment for 48 weeks

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 study is descriptive in nature and is not designed to provide analytical results regarding treatment response. The sample size is based on clinical and regulatory considerations and has no formal statistical basis. Please see attached Summary report

End point values	Baseline Arm	End Data		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	7		
Units: Number of Patients with Alterations	0	0		

Attachments (see zip file)	9730_EndOfTrialSummaryReport_signed_150517.pdf

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

SAEs will be collected for all patients and will be evaluated for duration and intensity.
SAEs will be collected for all patients from the first dose of rimantadine until 30 days after the last dose of treatment with rimantadine.

Adverse event reporting additional description:

Information about AEs, whether volunteered by the patient, discovered by the investigator through questioning or detected through physical examination, laboratory test or other investigation will be collected and recorded in the patient filecard and trial masterfile. A copy of all reported AEs will be sent to the sponsor if requested.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

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: Adverse event data can be requested from the scientific contact for the study, if required.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 July 2012	Patient information leaflet and Protocol amended to increase recruitment catchment and remove control group from the trial as recruitment was slower than expected.
29 October 2012	Amendment to the REC to include a patient information flyer, as clinical staff felt entire patient information sheet may be overwhelming to patients as the first introduction to the trial. Protocol Amended to include reference to leaflet

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.

None

Notes: