Clinical trial results:
Description of the evolution of plasma and urinary concentrations of iohexol in a cirrhotic patient population. "Pilot study on 9 patients"

Summary

EudraCT number	2018-002778-35
Trial protocol	FR
Global end of trial date	28 August 2019

Results information

Result version number	v1 (current)
This version publication date	04 July 2021
First version publication date	04 July 2021
Summary attachment (see zip file)	Statistical and safety analysis report (DFGHEP Statistical and safety analysis report FR 2020 02 25 - v 1.0.pdf) Summuray of Final report (DFGHEP Summary of final report 2020 06 11 - v 1.0.pdf)

Trial information

Trial identification

Sponsor protocol code	87RI18_0008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03769597
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Limoges University Hospital
Sponsor organisation address	2 Av Martin Luther King, Limoges, France, 87042
Public contact	Direction Research and Innovation, CHU de LIMOGES, +33 555058911, drc@chu-limoges.fr
Scientific contact	Direction Research and Innovation, Limoges University Hospital, +33 555058911, drc@chu-limoges.fr

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	11 June 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 August 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Describe the evolution of plasma and urinary concentrations of iohexol in a population of 9 cirrhotic patients from rich kinetics.

Protection of trial subjects:

The trial was carried out in accordance with the regulation, the ICH and the Helsinki declaration.
All patients have been informed and have given their consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 February 2019
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	France: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	8
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Thirteen patients were included (out of 9 required) between 02/11/2019 and 08/17/2019 because four were replaced (one secondary exclusion and three withdrawals of consent).
These patients were followed according to protocol.

Pre-assignment

Screening details:

Patients with advanced hepatic disease are recruited for consultation or hospitalization in the hepato-gastroenterology department by hepatologists. Recruitment takes place in the CHUs of Limoges over a period of 12 months.

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	Iohexol administration

Arm description:

After injecting a loading dose of 5ml of Iohexol Inj 300 MG/ML bolus, blood samples will be taken at given times for 24 hours. The urinary samples will be taken at each urination, with measurement of the exact volume and times

Arm type	Experimental
Investigational medicinal product name	OMNIPAQUE
Investigational medicinal product code	SUB08228MIG
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Solution for injection , Intravenous use

Dosage and administration details:

After injecting a loading dose of 5ml of Iohexol Inj 300 MG/ML bolus, blood samples will be taken at given times for 24 hours. The urinary samples will be taken at each urination, with measurement of the exact volume and times.

Number of subjects in period 1	Iohexol administration
Started	13
Completed	10
Not completed	3
Consent withdrawn by subject	3

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	13	13	
Age categorical Units: Subjects			
Adults (18-64 years)	8	8	
From 65-84 years	5	5	
Gender categorical Units: Subjects			
Female	0	0	
Male	13	13	

Subject analysis sets

Subject analysis set title	all patients
Subject analysis set type	Per protocol

Subject analysis set description:

A total of 9 patients were consecutively included in our study, exclusively men. It should be noted that during the inclusion period, 3 other patients were screened, signed their informed consent at the V0 visit, but secondarily withdrew their consent.

Reporting group values	all patients		
Number of subjects	10		
Age categorical Units: Subjects			
Adults (18-64 years)	6		
From 65-84 years	4		
Gender categorical Units: Subjects			
Female	0		
Male	10		

End points

End points reporting groups

Reporting group title	Iohexol administration

Reporting group description:

After injecting a loading dose of 5ml of Iohexol Inj 300 MG/ML bolus, blood samples will be taken at given times for 24 hours. The urinary samples will be taken at each urination, with measurement of the exact volume and times

Subject analysis set title	all patients
Subject analysis set type	Per protocol

Subject analysis set description:

A total of 9 patients were consecutively included in our study, exclusively men. It should be noted that during the inclusion period, 3 other patients were screened, signed their informed consent at the V0 visit, but secondarily withdrew their consent.

Primary: Description of the pharmacological curves of plasma and urinary concentrations of iohexol as a function of time

End point title	Description of the pharmacological curves of plasma and urinary concentrations of iohexol as a function of time

End point description:

End point type	Primary

End point timeframe:

0 minute, 15 minute, 30 minute, 1 hour, 90 minute, 2 hours, 3 hours, 4 hours, 6 hours, 8 hours, 12 hours, 24 hours

End point values	Iohexol administration	all patients		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10	10		
Units: mg d'I/mL				
number (not applicable)	0	0		

Statistical analyses

Statistical analysis title	Primary End point
Comparison groups	Iohexol administration v all patients
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	other
P-value	= 1 [1]
Method	Mixed models analysis

Notes:

[1] - no p-value defined

Adverse events

Adverse events information

Timeframe for reporting adverse events:

overall study

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	all patients

Reporting group description: -

Serious adverse events	all patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 10 (30.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Haemorrhagic ulcer			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute prostatitis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	all patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)		
General disorders and administration site conditions			
Extravasation blood			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		

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

None reported