Clinical trial results:
Chemoembolisation of patient with hepatocellular carcinoma, not selective for a curative treatment, by microsphere charged with idarubicin

Summary

EudraCT number	2014-000050-10
Trial protocol	FR
Global end of trial date	31 May 2018

Results information

Result version number	v1 (current)
This version publication date	13 July 2025
First version publication date	13 July 2025

Trial information

Trial identification

Sponsor protocol code	FFCD1307

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02185768
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fédération Francophone de Cancérologie Digestive
Sponsor organisation address	7 bd Jeanne d'Arc, Dijon, France, 21000
Public contact	Project manager, Fédération Francophone de cancérologie Digestive, 33 380393404, marie.moreau@u-bourgogne.fr
Scientific contact	Head of biostatistics, Fédération Francophone de cancérologie Digestive, 33 380668013, karine.le-malicot@u-bourgogne.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	Interim
Date of interim/final analysis	27 October 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 October 2017
Global end of trial reached?	Yes
Global end of trial date	31 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Objective response rate (complete and partial response) according to mRECIST at 6 months assessed in central review

Protection of trial subjects:

This trial was conducted in accordance with the New European Directive 2001/20/EC. The investigator undertook to obtain the patient's consent for the clinical and biological studies in writing, after providing adequate information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 January 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	France: 46
Worldwide total number of subjects	46
EEA total number of subjects	46

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)	14
From 65 to 84 years	28
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

Between January 2015 and June 2016, 46 study participants were included in seven centers. According to the protocol, an interim analysis was performed in January 2017 and the recruitment was stopped because of treatment efficacy.

Pre-assignment

Screening details:

Eligibility criteria were as follows: measurable targets according to the modified Response Evaluation Criteria in Solid Tumors (mRECIST) criteria ; Child-Pugh class A or B7 cirrhosis;
OMS performance status of 0 or 1; no previous chemotherapy, radiation therapy, or transarterial embolization (with or without chemotherapy) for HCC

Period 1

Period 1 title	Baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	IDASPHERE

Arm description:

TACE by using idarubicin-loaded beads

Arm type	Experimental
Investigational medicinal product name	Idarubicin + lodead beads
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Injection

Dosage and administration details:

After a loading time of 60 minutes, the solution containing idarubicin-loaded beads was transferred to a 30-mL syringe. Just before injection, the interventional radiologists
added 5 mL per milliliter of beads of a nonionic contrast medium (iodixanol [320 mg I/mL], Visto the syringe containing idarubicin-eluting beads. It was recommended to use 2.4-F to 2.8-F microcatheters for the catherization of tumor feeders, to perform cone-beam CT as soon as deemed necessary, and to inject the beads slowly (ideally 1 mL/min) through a 1-mL syringe until either complete delivery of the beads or reduced flow of the feeding artery with the conventional method of two to five heartbeats to clear the contrast column from the microcatheter tip

Number of subjects in period 1	IDASPHERE
Started	46
Treated patients	44
Completed	44
Not completed	2
Consent withdrawn by subject	1
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups

Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	46	46	
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)	14	14	
From 65-84 years	28	28	
85 years and over	4	4	
Gender categorical Units: Subjects			
Female	6	6	
Male	40	40	

Subject analysis sets

Subject analysis set title	mITT set
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Patients included in the study and who received the treatment

Reporting group values	mITT set		
Number of subjects	44		
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)	14		
From 65-84 years	27		
85 years and over	3		

Gender categorical Units: Subjects			
Female	6		
Male	38		

End points

End points reporting groups

Reporting group title	IDASPHERE
Reporting group description: TACE by using idarubicin-loaded beads	
Subject analysis set title	mITT set
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Patients included in the study and who received the treatment	

Primary: 6-month ORR by using mRECIST criteria

End point title	6-month ORR by using mRECIST criteria[1]
End point description:	
End point type	Primary
End point timeframe: within the 6 months after inclusion	

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: This study was a single-arm study so no inferential statistic was done only descriptive statistics

End point values	mITT set			
Subject group type	Subject analysis set			
Number of subjects analysed	44			
Units: patients				
Objective response rate at 6 months	23			
no objective response rate at 6 months	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival
End point description:	
End point type	Secondary
End point timeframe: Until the end of the follow-up or death (Whatever the cause)	

End point values	mITT set			
Subject group type	Subject analysis set			
Number of subjects analysed	44			
Units: months				
median (confidence interval 95%)	18.6 (11.7 to 29.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected before and after each chemoembolisation

Assessment type	Systematic

Dictionary used

Dictionary name	NCI-CTC
Dictionary version	4.0

Reporting groups

Reporting group title	mITT patients

Reporting group description: -

Serious adverse events	mITT patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 44 (34.09%)		
number of deaths (all causes)	30		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour necrosis			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Malignant hypertension			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyexia			

subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Delusion			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
C-Reactive protein increased			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Post embolisation syndrome			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Acsites			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varice oesophageal			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biloma			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic failure			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatorenal syndrome			

subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bacteraemia			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver abcess			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	mITT patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 44 (97.73%)		
Investigations			
ALAT increase			
subjects affected / exposed	31 / 44 (70.45%)		
occurrences (all)	31		
ASAT increase			
subjects affected / exposed	33 / 44 (75.00%)		
occurrences (all)	33		
Bilirubin increase			
subjects affected / exposed	27 / 44 (61.36%)		
occurrences (all)	27		
GGT increase			
subjects affected / exposed	27 / 44 (61.36%)		
occurrences (all)	27		
White blood cell decrease			
subjects affected / exposed	4 / 44 (9.09%)		
occurrences (all)	4		
Lipase increase			
subjects affected / exposed	4 / 44 (9.09%)		
occurrences (all)	4		
PNN decrease			
subjects affected / exposed	4 / 44 (9.09%)		
occurrences (all)	4		
Lymphocytes decrease			
subjects affected / exposed	12 / 44 (27.27%)		
occurrences (all)	12		
PAL increase			
subjects affected / exposed	16 / 44 (36.36%)		
occurrences (all)	16		
Platelets decrease			
subjects affected / exposed	23 / 44 (52.27%)		
occurrences (all)	23		
Vascular disorders			

Hypertension			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Nervous system disorders			
Cephalgia			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	16 / 44 (36.36%)		
occurrences (all)	16		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	7 / 44 (15.91%)		
occurrences (all)	7		
Fever			
subjects affected / exposed	17 / 44 (38.64%)		
occurrences (all)	17		
Gastrointestinal disorders			
Stomach pain			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Abdominal pain			
subjects affected / exposed	5 / 44 (11.36%)		
occurrences (all)	5		
Nausea			
subjects affected / exposed	4 / 44 (9.09%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Hypercalcemia			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Hyperglycemia			
subjects affected / exposed	23 / 44 (52.27%)		
occurrences (all)	23		
Hyperkaliemia			

subjects affected / exposed	4 / 44 (9.09%)		
occurrences (all)	4		
Hypoalbuminemia			
subjects affected / exposed	21 / 44 (47.73%)		
occurrences (all)	21		
Hypocalcemia			
subjects affected / exposed	5 / 44 (11.36%)		
occurrences (all)	5		
Hypokaliemia			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Hypomagnesemia			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Hyponatremia			
subjects affected / exposed	15 / 44 (34.09%)		
occurrences (all)	15		
Hypophosphatemia			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		

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? Yes

Date	Interruption	Restart date
27 October 2017	Study was interrupted at the 1st interim analysis for efficacy purpose	-

Notes:

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/31038408