



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 + Iodead 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 catheterization 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 | | |
| Pyrexia | | | |

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

| | | | |
|-----------------------------|------------------|--|--|
| 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>