# Clinical trial results:
# Chemotherapy and Cetuximab in Patients Undergoing Surgery for Peritoneal Carcinomatosis From Colorectal Cancer (COCHISE)

## Summary

| | |
|---|---|
| EudraCT number | 2006-003900-20 |
| Trial protocol | FR |
| Global end of trial date | 17 September 2013 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 20 January 2022 |
| First version publication date | 20 January 2022 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | IB 2006-30 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00766142 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Institut Bergonié |
| Sponsor organisation address | 229 cours de l'Argonne, Bordeaux, France, 33076 |
| Public contact | Regulatory Affairs Management Desk, Institut Bergonié, drci@bordeaux.unicancer.fr |
| Scientific contact | Regulatory Affairs Management Desk, Institut Bergonié, drci@bordeaux.unicancer.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 | 17 September 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 17 September 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 17 September 2013 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

Evaluer en termes de survie sans progression à 3 ans une chimiothérapie systémique associée au Cetuximab en traitement adjuvant chez des patients complètement réséqués par chirurgie de leur carcinose péritonéale isolée d'origine colorectale (seuls les patients aptes à recevoir de la chimiothérapie sont évalués).

Protection of trial subjects:

A supervisory committee is constitued to evaluate the benefit/risk ratio along the study period.

Background therapy:

Drugs used in chemotherapy, such as oxaliplatin, leucovorin, and fluorouracil, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Monoclonal antibodies, such as cetuximab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Giving more than one drug (combination chemotherapy) together with cetuximab may kill more tumor cells.

This phase II trial is studying how well chemotherapy given together with cetuximab works in treating patients undergoing surgery to remove peritoneal carcinomatosis from colorectal cancer.

Evidence for comparator:

Single arm trial. No comparator.

| | |
|---|---|
| Actual start date of recruitment | 09 November 2007 |
| 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 | France: 14 |
| Worldwide total number of subjects | 14 |
| EEA total number of subjects | 14 |

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 | 0 |

| | |
|---|---|
| months) | |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 12 |
| From 65 to 84 years | 2 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Patients>18 years with histologically proven CRPC and no other metastatic disease (liver, lungs, lymphadenopathy, etc.) who signed a written informed consent and had French social security were included in the study. There was no upper age limit, but an oncogeriatric assessment was required for patients>75 years of age.

### Pre-assignment

Screening details:

Colorectal Cancer
Primary Peritoneal Cavity Cancer

### Period 1

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

Blinding implementation details:

Not applicable / not blinded / single-arm trial

### Arms

| | |
|---|---|
| **Arm title** | Chemotherapy + Cetuximab |

Arm description:

Cetuximab 500 mg/m² IV
Oxaliplatine 85 mg/m² IV
L-folinique Acid 200 mg/m² (or 400 mg/m² for DL) IV
5-FU bolus 400 mg/m² IV
5-FU continu 2400 mg/m² IV. One cycle = 14 days. Up to 12 cycles.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Cetuximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Cetuximab 500 mg/m² IV
One cycle = 14 days. Up to 12 cycles.

| | |
|---|---|
| Investigational medicinal product name | Oxaliplatine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Oxaliplatine 85 mg/m² IV
One cycle = 14 days. Up to 12 cycles.

| | |
|---|---|
| Investigational medicinal product name | L-folinique Acid |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

L-folinique Acid 200 mg/m² (or 400 mg/m² for DL) IV
One cycle = 14 days. Up to 12 cycles.

| | |
|---|---|
| Investigational medicinal product name | 5 – fluorouracile |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Intravenous bolus use |

Dosage and administration details:

5-FU bolus 400 mg/m² IV
One cycle = 14 days. Up to 12 cycles.

| | |
|---|---|
| Investigational medicinal product name | 5 – fluorouracile |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

5-FU continu 2400 mg/m² IV.
One cycle = 14 days. Up to 12 cycles.

| **Number of subjects in period 1** | Chemotherapy + Cetuximab |
|---|---|
| Started | 14 |
| Completed | 14 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Chemotherapy + Cetuximab |
| Reporting group description: | |
| Cetuximab 500 mg/m² IV<br>Oxaliplatine 85 mg/m² IV<br>L-folinique Acid 200 mg/m² (or 400 mg/m² for DL) IV<br>5-FU bolus 400 mg/m² IV<br>5-FU continu 2400 mg/m² IV. One cycle = 14 days. Up to 12 cycles. | |

| Reporting group values | Chemotherapy + Cetuximab | Total | |
|---|---|---|---|
| Number of subjects | 14 | 14 | |
| Age categorical<br>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) | | 0 | |
| From 65-84 years | | 0 | |
| 85 years and over | | 0 | |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 61.9 | | |
| standard deviation | ± 5.15 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 4 | 4 | |
| Male | 10 | 10 | |

## End points

### End points reporting groups

| Reporting group title | Chemotherapy + Cetuximab |
|---|---|

Reporting group description:

Cetuximab 500 mg/m² IV
Oxaliplatine 85 mg/m² IV
L-folinique Acid 200 mg/m² (or 400 mg/m² for DL) IV
5-FU bolus 400 mg/m² IV
5-FU continu 2400 mg/m² IV. One cycle = 14 days. Up to 12 cycles.

### Primary: Median Progression-free Survival (PFS) Time

| End point title | Median Progression-free Survival (PFS) Time[1] |
|---|---|

End point description:

| End point type | Primary |
|---|---|

End point timeframe:

Since surgery, up to 5 years

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: Single arm trial - There was no statistical test performed.

| End point values | Chemotherapy + Cetuximab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 14 | | | |
| Units: months | | | | |
| median (confidence interval 95%) | 12.2 (6.5 to 17.3) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: 30-day Mortality Rate

| End point title | 30-day Mortality Rate |
|---|---|

End point description:

Rate of deaths observed within 30 days of surgery

| End point type | Secondary |
|---|---|

End point timeframe:

from the date of surgery up to 30 days

| End point values | Chemotherapy + Cetuximab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 14 | | | |
| Units: Subjects | 0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Number of Adverse Events Per Patient, Within 30 Days of Surgery

| End point title | Mean Number of Adverse Events Per Patient, Within 30 Days of Surgery |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

from the date of surgery up to 30 days

| End point values | Chemotherapy + Cetuximab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 14 | | | |
| Units: Mean number of AE per subject | | | | |
| arithmetic mean (confidence interval 95%) | 0.93 (0 to 3.7) | | | |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

The adverse event are reported from the signature of the informed consent form to the study end participation of the patient

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 10 |

### Reporting groups

| | |
|---|---|
| Reporting group title | All subjects |

Reporting group description: -

| Serious adverse events | All subjects | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 14 (42.86%) | | |
| number of deaths (all causes) | 8 | | |
| number of deaths resulting from adverse events | 1 | | |
| Injury, poisoning and procedural complications | | | |
| Intraoperative gastrointestinal injury | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Vascular disorders - Other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| General disorders and administration site conditions - Other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Immune system disorders | | | |
| Anaphylaxis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Gastrointestinal disorders - Other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diarrhea | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Urinary fistula | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| 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** | All subjects | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 14 / 14 (100.00%) | | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Flushing | | | |
| subjects affected / exposed | 4 / 14 (28.57%) | | |
| occurrences (all) | 4 | | |
| Hot flashes | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| General disorders and administration site conditions | | | |
| General disorders and administration site conditions - Other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Fatigue | | | |
| subjects affected / exposed | 10 / 14 (71.43%) | | |
| occurrences (all) | 10 | | |
| Fever | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Chills | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Injection site reaction | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Edema limbs | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Pain | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Pain, other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Immune system disorders | | | |
| Allergic reaction | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Reproductive system and breast disorders | | | |
| Vaginal discharge | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Dyspnea | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Investigations | | | |
| White blood cell decreased | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 3 / 14 (21.43%) | | |
| occurrences (all) | 4 | | |
| Platelet count decreased | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Weight los | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Injury, poisoning and procedural complications | | | |
| burn | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Injury, poisoning and procedural complications - Other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Nervous system disorders | | | |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Peripheral sensory neuropathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 13 / 14 (92.86%) | | |
| occurrences (all) | 14 | | |
| Blood and lymphatic system disorders | | | |
| Blood and lymphatic system disorders - Other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Anemia | | | |
| subjects affected / exposed | 3 / 14 (21.43%) | | |
| occurrences (all) | 3 | | |
| Gastrointestinal disorders | | | |
| Constipation | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Diarrhea | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Gastritis | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Small intestinal mucositis | | | |
| subjects affected / exposed | 4 / 14 (28.57%) | | |
| occurrences (all) | 4 | | |
| Nausea | | | |
| subjects affected / exposed | 3 / 14 (21.43%) | | |
| occurrences (all) | 3 | | |
| Vomiting | | | |
| subjects affected / exposed | 4 / 14 (28.57%) | | |
| occurrences (all) | 5 | | |
| Skin and subcutaneous tissue disorders | | | |
| Skin and subcutaneous tissue disorders - Other | | | |
| subjects affected / exposed | 7 / 14 (50.00%) | | |
| occurrences (all) | 7 | | |
| Dry skin | | | |
| subjects affected / exposed | 4 / 14 (28.57%) | | |
| occurrences (all) | 4 | | |
| Pruritus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Rash acneiform | | | |
| subjects affected / exposed | 7 / 14 (50.00%) | | |
| occurrences (all) | 7 | | |
| Palmar-plantar erythrodysesthesia syndrome | | | |
| subjects affected / exposed | 7 / 14 (50.00%) | | |
| occurrences (all) | 7 | | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal and connective tissue disorder - Other | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 3 | | |
| Trismus | | | |
| subjects affected / exposed | 2 / 14 (14.29%) | | |
| occurrences (all) | 2 | | |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 3 / 14 (21.43%) | | |
| occurrences (all) | 3 | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 14 (7.14%) | | |
| occurrences (all) | 1 | | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 30 May 2007 | Protocol V3 dated 21-may-2007 |
| 30 May 2007 | Protocol V2 dated 02-may-2007 |
| 23 September 2008 | Protocol V4 dated 01-aug-2008 |
| 28 April 2010 | Protocol V5 dated 26-mar-2010 |
| 11 October 2012 | Protocol V6.1 dated 27-sep-2012 |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|---|---|---|
| 21 August 2013 | Supervisory committee proposal | - |

Notes:

### Limitations and caveats

None reported

### Online references

http://www.ncbi.nlm.nih.gov/pubmed/31331370