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 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.	

Reporting group values	Chemotherapy + Cetuximab	Total	
Number of subjects	14	14	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	61.9		
standard deviation	± 5.15	-	
Gender categorical 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