Clinical trial results:
Fluorouracil, Cisplatin, Leucovorin Calcium, and Cetuximab in Treating Patients With Adenocarcinoma of the Stomach or Gastroesophageal Junction

Summary

EudraCT number	2010-023115-33
Trial protocol	FR
Global end of trial date	04 November 2019

Results information

Result version number	v1 (current)
This version publication date	06 February 2026
First version publication date	06 February 2026

Trial information

Trial identification

Sponsor protocol code	FFCD 0901

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01360086
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fédération Francophone de Cancérologie Digestive (FFCD)
Sponsor organisation address	7 Boulevard Jeanne d'Arc - BP 87900, DIJON, France, 21079
Public contact	Carole Monterymard, Fédération Francophone de Cancérologie Digestive, carole.monterymard@u-bourgogne.fr
Scientific contact	Carole Monterymard, Fédération Francophone de Cancérologie Digestive, carole.monterymard@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	Final
Date of interim/final analysis	04 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 July 2016
Global end of trial reached?	Yes
Global end of trial date	04 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial :
to evaluate the objective response rate according to RECIST V1.1 criteria in patients with adenocarcinoma of the stomach or gastroesophageal junction treated with neoadjuvant chemotherapy comprising fluorouracil, cisplatin, leucovorin calcium, and cetuximab followed by surgery and adjuvant chemotherapy.
to determine the non-toxicity rate in these patients.

Protection of trial subjects:

This open-label non-randomized single arm multicenter phase II study was conducted in 25 centers in France; approved by the independent ethics committees of the participating sites; and designed and conducted according to good clinical practice, the Declaration of Helsinki, and all local requirements. All patients gave written informed consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 June 2011
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: 65
Worldwide total number of subjects	65
EEA total number of subjects	65

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)	45

From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From June 2011 to March 2013, 65 patients were enrolled in the trial by 25 centers in France.

Pre-assignment

Screening details:

Before enrollement, standard examinations (biological, clinical, ...) were done. In terms of imaging, thoracic and abdominal CT scans were also done.

Period 1

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

Blinding implementation details:

no blinding

Arms

Arm title	neoadjuvant therapy + surgery + adjuvant therapy

Arm description:

Neoadjuvant therapy and surgery: Patients receive leucovorin calcium IV over 2 hours, cisplatin IV, fluorouracil IV continuously over 46 hours, and cetuximab IV over 1-2 hours on day 1. Treatment repeats every 2 weeks for 6 courses in the absence of disease progression or unacceptable toxicity. Within 3-4 weeks after completing neoadjuvant chemotherapy, patients undergo surgery.
Adjuvant therapy: Within 4-8 weeks after completing neoadjuvant chemotherapy, patients receive leucovorin calcium, cisplatin, fluorouracil, and cetuximab as in neoadjuvant therapy. Treatment repeats every 2 weeks for 6 courses in the absence of disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

6 cycles of intravenous Cetuximab (500mg/m²) every two weeks

Investigational medicinal product name	Cisplatine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

6 cycles of intravenous Cisplatine (50mg/m²) every 2 weeks.

Investigational medicinal product name	LV5FU2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

6 cycles of intravenous LV5FU2s (folinic acid 400mg/m², 5FU bolus 400mg/m², and continuous infusion of 5FU 2400mg/m²) every 2 weeks.

Number of subjects in period 1	neoadjuvant therapy + surgery + adjuvant therapy
Started	65
Completed	64
Not completed	1
patient without imagery	1

Baseline characteristics

Reporting groups	
Reporting group title	ITT

Reporting group description: -

Reporting group values	ITT	Total	
Number of subjects	65	65	
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)	45	45	
From 65-84 years	20	20	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	11	11	
Male	54	54	

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

Subject analysis set description:

all patients who received at least one dose of the study drug (neoadjuvant therapy) and who have a control imagery at inclusion and before surgery.

Reporting group values	mITT		
Number of subjects	64		
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)	45		
From 65-84 years	19		
85 years and over	0		

Gender categorical Units: Subjects			
Female	10		
Male	54		

End points

End points reporting groups

Reporting group title	neoadjuvant therapy + surgery + adjuvant therapy

Reporting group description:

Neoadjuvant therapy and surgery: Patients receive leucovorin calcium IV over 2 hours, cisplatin IV, fluorouracil IV continuously over 46 hours, and cetuximab IV over 1-2 hours on day 1. Treatment repeats every 2 weeks for 6 courses in the absence of disease progression or unacceptable toxicity. Within 3-4 weeks after completing neoadjuvant chemotherapy, patients undergo surgery.
Adjuvant therapy: Within 4-8 weeks after completing neoadjuvant chemotherapy, patients receive leucovorin calcium, cisplatin, fluorouracil, and cetuximab as in neoadjuvant therapy. Treatment repeats every 2 weeks for 6 courses in the absence of disease progression or unacceptable toxicity.

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

Subject analysis set description:

all patients who received at least one dose of the study drug (neoadjuvant therapy) and who have a control imagery at inclusion and before surgery.

Primary: rate of objective response

End point title	rate of objective response[1]

End point description:

The primary end point consisted of the rate of tumor objective response according to RECIST V1.1 criteria on CT scans (patients with a complete or partial response)

End point type	Primary

End point timeframe:

At 3 weeks after the end of neoadjuvant therapy

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 is a single arm study. So no inferential statistic was done.

End point values	mITT			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: Patients				
response objective	19			
no response objective	45			

Statistical analyses

No statistical analyses for this end point

Primary: major toxicities

End point title	major toxicities[2]

End point description:

The primary end point consisted of the rate of patients with major toxicities resulting in discontinuation in the neoadjuvant CT setting.
CT treatment was stopped in the following cases: investigator’s decision, or major toxicity or adverse event (AE), or disease progression, or patient’s decision.

End point type	Primary

End point timeframe:

at 3 weeks after the end of the neoadjuvant chemotherapy

Notes:

[2] - 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 is a single arm study. So no inferential statistic was done.

End point values	mITT			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: Patients				
stop for major toxicities	3			
no stop for major toxicities	61			

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Free Survival at 3 years

End point title	Disease Free Survival at 3 years

End point description:

End point type	Secondary

End point timeframe:

at 3 years after the date of inclusion

End point values	neoadjuvant therapy + surgery + adjuvant therapy			
Subject group type	Reporting group			
Number of subjects analysed	65			
Units: months				
median (confidence interval 95%)	24.38 (16.39 to 39.43)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs (related and unrelated, expected and unexpected) occurring in the course of the study, from the inclusion and until 30 days after the last dose of the neoadjuvant CT drug were reported by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	NCI-CTC
Dictionary version	4

Reporting groups

Reporting group title	Safety population

Reporting group description:

all patients who received at least one dose of the study drug (neoadjuvant CT)

Serious adverse events	Safety population		
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 65 (49.23%)		
number of deaths (all causes)	36		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
tumor ulceration			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Jugular vein thrombosis			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			

subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Postoperative care				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Condition aggravated				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Implant site extravasation				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Discomfort				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombosis in device				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	2 / 65 (3.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchial fistula			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	2 / 65 (3.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	9 / 65 (13.85%)		
occurrences causally related to treatment / all	8 / 9		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
gastric syndrome			

subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
anemia			
subjects affected / exposed	2 / 65 (3.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	2 / 65 (3.08%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysphagia			

subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
fecal impaction				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	2 / 65 (3.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal necrosis				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis necrotising				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyloric stenosis				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				

Renal failure				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute kidney failure				
subjects affected / exposed	2 / 65 (3.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Renal vein thrombosis				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Fistula				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Device-related septicemia				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mediastinal abscess				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Peritonitis				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	4 / 65 (6.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	2 / 65 (3.08%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdiaphragmatic abscess				
subjects affected / exposed	2 / 65 (3.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypomagnesaemia				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypophosphataemia				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
undernutrition				

subjects affected / exposed	1 / 65 (1.54%)		
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	Safety population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 65 (100.00%)		
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 65 (7.69%)		
occurrences (all)	5		
Gamma-glutamyltransferase increased			
subjects affected / exposed	17 / 65 (26.15%)		
occurrences (all)	17		
White blood cell count decreased			
subjects affected / exposed	37 / 65 (56.92%)		
occurrences (all)	37		
Neutrophil count decreased			
subjects affected / exposed	37 / 65 (56.92%)		
occurrences (all)	37		
PAL increased			
subjects affected / exposed	6 / 65 (9.23%)		
occurrences (all)	6		
Platelet count decreased			
subjects affected / exposed	35 / 65 (53.85%)		
occurrences (all)	35		
Vascular disorders			
Arterial thrombosis			
subjects affected / exposed	4 / 65 (6.15%)		
occurrences (all)	4		
Thrombosis			
subjects affected / exposed	6 / 65 (9.23%)		
occurrences (all)	6		

Nervous system disorders Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	 7 / 65 (10.77%) 7		
Blood and lymphatic system disorders anemia subjects affected / exposed occurrences (all)	 53 / 65 (81.54%) 53		
General disorders and administration site conditions Headache subjects affected / exposed occurrences (all) Pain subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) fever subjects affected / exposed occurrences (all) Vertigo subjects affected / exposed occurrences (all)	 5 / 65 (7.69%) 5 18 / 65 (27.69%) 18 50 / 65 (76.92%) 50 9 / 65 (13.85%) 9 5 / 65 (7.69%) 5		
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	 7 / 65 (10.77%) 7		
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Diarrhoea	 30 / 65 (46.15%) 30 5 / 65 (7.69%) 5		

subjects affected / exposed occurrences (all) mucositis subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	25 / 65 (38.46%) 25 37 / 65 (56.92%) 37 45 / 65 (69.23%) 45 29 / 65 (44.62%) 29		
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all)	 5 / 65 (7.69%) 5 7 / 65 (10.77%) 7		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all) acneiform rash subjects affected / exposed occurrences (all) Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all) Xerosis subjects affected / exposed occurrences (all) Dry mouth subjects affected / exposed occurrences (all)	 14 / 65 (21.54%) 14 55 / 65 (84.62%) 55 7 / 65 (10.77%) 7 28 / 65 (43.08%) 28 7 / 65 (10.77%) 7		
Infections and infestations			

Infection			
subjects affected / exposed	7 / 65 (10.77%)		
occurrences (all)	7		
Metabolism and nutrition disorders			
Weight decreased			
subjects affected / exposed	7 / 65 (10.77%)		
occurrences (all)	7		
anorexia			
subjects affected / exposed	36 / 65 (55.38%)		
occurrences (all)	36		
Dysgeusia			
subjects affected / exposed	4 / 65 (6.15%)		
occurrences (all)	4		
Dysphagia			
subjects affected / exposed	11 / 65 (16.92%)		
occurrences (all)	11		
Hyperglycaemia			
subjects affected / exposed	5 / 65 (7.69%)		
occurrences (all)	5		
Hypoalbuminaemia			
subjects affected / exposed	4 / 65 (6.15%)		
occurrences (all)	4		
Hypokalaemia			
subjects affected / exposed	5 / 65 (7.69%)		
occurrences (all)	5		
Hypomagnesaemia			
subjects affected / exposed	4 / 65 (6.15%)		
occurrences (all)	4		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/37046849