Clinical trial results:
FFCD 1102
ETUDE DE PHASE II : TRAITEMENT DE PREMIERE LIGNE PAR FOLFIRINOX POUR LES PATIENTS AYANT UN CANCER DU RECTUM AVEC METASTASES SYNCHRONES NON RESECABLES

Summary

EudraCT number	2011-006266-41
Trial protocol	FR
Global end of trial date	13 March 2017

Results information

Result version number	v1 (current)
This version publication date	05 July 2025
First version publication date	05 July 2025

Trial information

Trial identification

Sponsor protocol code	FFCD 1102

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01674309
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fédération Francophone de Cancérologie Digestive (FFCD)
Sponsor organisation address	Faculté de Médecine, 7 Boulevard Jeanne d'Arc, BP 87900, Dijon, France, 21079
Public contact	Marie Moreau, Fédération Francophone de Cancérologie Digestive (FFCD), +33 755676632, marie.moreaut@u-bourgogne.fr
Scientific contact	Marie Moreau, Fédération Francophone de Cancérologie Digestive (FFCD), +33 755676632, marie.moreaut@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	14 March 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 December 2015
Global end of trial reached?	Yes
Global end of trial date	13 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to investigate the tumoral control rate(Complete response or Partial response or stability) at 4 months, according to the RECIST criteria (version 1.1).

Protection of trial subjects:

This trial was conducted in accordance with the European Directive 2001/20/EC. The investigator undertook to obtain the patient's consent for the clinical trial in writing, after providing adequate information (information sheets and consent forms in Appendices). The study protocol was approved by the French ethics committee 'CCP Ile de France 8'.

Background therapy:

The FOLFIRINOX protocol (folinic acid, 5 FU, oxaliplatin, irinotecan) appeared to be a promising protocol as an initial treatment with an objective response rate of about 70%.

Evidence for comparator: -

Actual start date of recruitment	12 July 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	2 Years
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)	42
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From July 2012 to February 2015, 65 patients with rectal cancer and synchronous metastases were included in the study and treated in 22 participating French centres.

Pre-assignment

Screening details:

Before enrollement, standard examinations (biological, clinical, ECG, coloscopy) and quality of life evaluations (QLQ-C30 + CR29) were done. In terms of imaging, abdominal and pelvic computed tomography scan and MRI and rectosigmoidoscopy were also done.

Period 1

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

Blinding implementation details:

Not blinded

Arms

Arm title	FOLFIRINOX

Arm description:

FOLFIRINOX induction : 8 planned cycles.

Arm type	Experimental
Investigational medicinal product name	FOLFIRINOX
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

FOLFIRINOX regimen: oxaliplatin 85 mg/m2 d1 + irinotecan 180 mg/m2 d1 + leucovorin 400 mg/m2 d1 followed by 5FU 400 mg/m2 bolus d1 and 2,400 mg/m2 46h continuous infusion biweekly

Number of subjects in period 1	FOLFIRINOX
Started	65
Completed	56
Not completed	9
Adverse event, serious fatal	1
Physician decision	2
Tumor regression	1
Adverse event, non-fatal	1
Diabetic foot requiring surgical management	1
Progression	3

Baseline characteristics

Reporting groups	
Reporting group title	Baseline period

Reporting group description: -

Reporting group values	Baseline period	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)	42	42	
From 65-84 years	23	23	
85 years and over	0	0	
Age continuous Units: years			
median	61		
full range (min-max)	34 to 78	-	
Gender categorical Units: Subjects			
Female	14	14	
Male	51	51	
ECOG PS Units: Subjects			
PS 0	24	24	
PS1	40	40	
PS 2	1	1	
Rectal tumour			
in MRI (magnetic resonance imaging) central review			
Units: Subjects			
Lower	22	22	
Middle	35	35	
Upper	5	5	
Missing	3	3	
Differenciation grade Units: Subjects			
Well	23	23	
Moderate	23	23	
Poor	3	3	
Unknown	16	16	
T stage at diagnosis			
in MRI (magnetic resonance imaging) central review			

Units: Subjects			
T2	3	3	
T3	13	13	
T4	42	42	
Missing	7	7	
Mutational status Units: Subjects			
RAS mutated	29	29	
BRAF mutated	3	3	
RAS/BRAF non mutated	23	23	
Unknown	10	10	
Number of metastatic sites Units: Subjects			
One	24	24	
>= 2	41	41	

End points

End points reporting groups

Reporting group title	FOLFIRINOX

Reporting group description:

FOLFIRINOX induction : 8 planned cycles.

Primary: 4-month disease control rate

End point title	4-month disease control rate[1]

End point description:

Disease control (Complete response or Partial response or stability) at 4 months according to RECIST 1.1 and assessed by central review.

End point type	Primary

End point timeframe:

4 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: The study was a single-arm study that's why no statistical analyses was done.

End point values	FOLFIRINOX			
Subject group type	Reporting group			
Number of subjects analysed	64[2]			
Units: patients				
Disease control	60			
No disease control	4			

Notes:

[2] - One patient was excluded because of death unrelated to study treatment after the first cycle

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival

End point title	Progression-free survival

End point description:

Progression free-survival was measured from inclusion to the date of the first documented progression or relapse (in the case of R0/R1 resections of rectal tumor and metastases) or death from any cause. Patients alive without progression were censored at the last follow-up.

End point type	Secondary

End point timeframe:

until the last follow-up or the apperance of progression or death

End point values	FOLFIRINOX			
Subject group type	Reporting group			
Number of subjects analysed	65			
Units: months				
median (confidence interval 95%)	10.9 (8.8 to 12.9)			

Attachments (see zip file)	PFS and OS in the ITT population/Figure 2.tiff

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival

End point description:

Overall survival was defined as the time between inclusion and death (all causes). Patients alive were censored at the last follow-up.

End point type	Secondary

End point timeframe:

until the end of the follow-up or death (Whatever the cause)

End point values	FOLFIRINOX			
Subject group type	Reporting group			
Number of subjects analysed	65			
Units: months				
median (confidence interval 95%)	33.4 (22.6 to 38.2)			

Attachments (see zip file)	PFS and OS in the ITT population/Figure 2.tiff

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected after each cycles of treatment until the end of the treatment period.

Assessment type	Systematic

Dictionary used

Dictionary name	NCI-CTC
Dictionary version	4.0

Reporting groups

Reporting group title	FOLFIRINOX

Reporting group description:

FOLFIRINOX induction : 8 planned cycles.

Serious adverse events	FOLFIRINOX		
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 65 (21.54%)		
number of deaths (all causes)	41		
number of deaths resulting from adverse events	1		
Investigations			
Weight loss			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor-related fever			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Reaction in relation to perfusion			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Ischemic stroke			

subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Fever			
subjects affected / exposed	2 / 65 (3.08%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Phlebitis at the catheter site			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General deterioration of health			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthermia			
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			
Febrile neutropenia			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Agranulocytosis			
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			
Diarrhea			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Abdominal pain				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 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			
Intestinal obstruction				
subjects affected / exposed	2 / 65 (3.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Subileus				
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				
Pulmonary embolism				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
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				
Hyperbilirubinemia				
subjects affected / exposed	1 / 65 (1.54%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Diabetic foot				

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			
Staphylococcal septic arthritis			
subjects affected / exposed	1 / 65 (1.54%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes			
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	FOLFIRINOX		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 65 (100.00%)		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	20 / 65 (30.77%)		
occurrences (all)	20		
Aspartate aminotransferase increased			
subjects affected / exposed	23 / 65 (35.38%)		
occurrences (all)	23		
Creatinine increased			
subjects affected / exposed	6 / 65 (9.23%)		
occurrences (all)	6		
Gamma-glutamyltransferase increased			
subjects affected / exposed	37 / 65 (56.92%)		
occurrences (all)	37		
White blood cell count decreased			

subjects affected / exposed occurrences (all) Lymhocytes decreased subjects affected / exposed occurrences (all) Neutrophils decreased subjects affected / exposed occurrences (all) Weight loss subjects affected / exposed occurrences (all) Phosphatases Alcalines increased subjects affected / exposed occurrences (all)	33 / 65 (50.77%) 33 26 / 65 (40.00%) 26 42 / 65 (64.62%) 42 27 / 65 (41.54%) 27 53 / 65 (81.54%) 53		
Vascular disorders Thromboembolic event subjects affected / exposed occurrences (all)	 7 / 65 (10.77%) 7		
Nervous system disorders Dysgueusia subjects affected / exposed occurrences (all) Peripheral neuropathy subjects affected / exposed occurrences (all) Paresthesia subjects affected / exposed occurrences (all)	 8 / 65 (12.31%) 18 48 / 65 (73.85%) 48 35 / 65 (53.85%) 35		
Blood and lymphatic system disorders Anemia subjects affected / exposed occurrences (all) Thrombocytopenia subjects affected / exposed occurrences (all)	 55 / 65 (84.62%) 55 33 / 65 (50.77%) 33		
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	55 / 65 (84.62%)		
occurrences (all)	55		
Fever			
subjects affected / exposed	11 / 65 (16.92%)		
occurrences (all)	11		
Immune system disorders			
Allergic reaction			
subjects affected / exposed	4 / 65 (6.15%)		
occurrences (all)	4		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	14 / 65 (21.54%)		
occurrences (all)	14		
Diarrhoea			
subjects affected / exposed	49 / 65 (75.38%)		
occurrences (all)	49		
Abdominal pain			
subjects affected / exposed	17 / 65 (26.15%)		
occurrences (all)	17		
Nausea			
subjects affected / exposed	37 / 65 (56.92%)		
occurrences (all)	37		
Stomatitis			
subjects affected / exposed	19 / 65 (29.23%)		
occurrences (all)	19		
Vomiting			
subjects affected / exposed	18 / 65 (27.69%)		
occurrences (all)	18		
Respiratory, thoracic and mediastinal disorders			
Dyspnea			
subjects affected / exposed	5 / 65 (7.69%)		
occurrences (all)	5		
Epistaxis			
subjects affected / exposed	6 / 65 (9.23%)		
occurrences (all)	6		

Cough			
subjects affected / exposed	6 / 65 (9.23%)		
occurrences (all)	6		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	27 / 65 (41.54%)		
occurrences (all)	27		
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	5 / 65 (7.69%)		
occurrences (all)	5		
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	4 / 65 (6.15%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	18 / 65 (27.69%)		
occurrences (all)	18		
Hyperglycemia			
subjects affected / exposed	4 / 65 (6.15%)		
occurrences (all)	4		
Hypokaliemia			
subjects affected / exposed	8 / 65 (12.31%)		
occurrences (all)	8		
Hyponatremia			
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/30343254