Clinical trial results:
Radiosensitizing Chemotherapy (Irinotecan) with Stereotactic Body Radiation Therapy for the Treatment of Inoperable Liver and/or Lung Metastases of Colorectal Cancer

Summary

EudraCT number	2006-005440-87
Trial protocol	FR
Global end of trial date	31 October 2017

Results information

Result version number	v1 (current)
This version publication date	29 March 2022
First version publication date	29 March 2022

Trial information

Trial identification

Sponsor protocol code	BRD 06/9-R

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01220063
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	INSTITUT DE CANCEROLOGIE DE L'OUEST
Sponsor organisation address	15 rue André Boquel, ANGERS 02, France, 49055
Public contact	Marine TIGREAT, INSTITUT DE CANCEROLOGIE DE L'OUESTT, +33 240679747, promotionrc@ico.unicancer.fr
Scientific contact	Marine TIGREAT, INSTITUT DE CANCEROLOGIE DE L'OUEST, +33 240679747, promotionrc@ico.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	30 October 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2017
Global end of trial reached?	Yes
Global end of trial date	31 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary outcome was the objective local response rate as per RECIST 1.0.

Protection of trial subjects:

The sponsor contracted with insurance to cover all risk related to the trial.
The study protocol has been approved by the French drug regulatory agency (ANSM) and the French ethical committee (CPP Ouest V).
Every investigator approved in writing to conduct patients' treatment and monitoring in accordance with the protocol.
Patient under protection within the meaning of the French legislation were not eligible to the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2007
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	4 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 47
Worldwide total number of subjects	47
EEA total number of subjects	47

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)	21

From 65 to 84 years	26
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The first patient signed consent on 10/19/2007 and was included on 10/2007. The last patient was included on 6/26/2014.

Pre-assignment

Screening details:

During a standard consultation, the medical oncologist presents the study to the patient with liver or lung metatases of colorectal cancer. He gives the patient the consent form to participate in the study. Patients will be able to sign ICF after a reflection period if they deem it necessary or on the day the information is given.
Once the cons

Period 1

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

Arms

Arm title	Irinotecan + SBRT

Arm description: -

Arm type	Experimental
Investigational medicinal product name	CAMPTO
Investigational medicinal product code	
Other name	Irinotecan
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Two weekly 40mg/m2 intravenous infusions

Number of subjects in period 1	Irinotecan + SBRT
Started	47
Completed	47

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	47	47	
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)	21	21	
From 65-84 years	26	26	
85 years and over	0	0	
Age continuous Units: years			
median	69.4		
full range (min-max)	46 to 84	-	
Gender categorical Units: Subjects			
Female	20	20	
Male	27	27	

End points

End points reporting groups

Reporting group title	Irinotecan + SBRT

Reporting group description: -

Primary: Primary efficacy endpoint

End point title	Primary efficacy endpoint[1]

End point description:

End point type	Primary

End point timeframe:

one year

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 - No stastistical analyse was performed

End point values	Irinotecan + SBRT			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percent				
number (confidence interval 84.2%)	84.2 (69.7 to 92.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From consent until 30 days after the end of traitment

Assessment type	Systematic

Dictionary used

Dictionary name	CTC-AE
Dictionary version	3.0

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 44 (15.91%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Budd-Chiari syndrome			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Jaundice			
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			
Pneumothorax			
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			
Septic shock			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Sepsis			
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	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 44 (88.64%)		
General disorders and administration site conditions			
anorexia			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Asthenia			
subjects affected / exposed	13 / 44 (29.55%)		
occurrences (all)	16		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	17 / 44 (38.64%)		
occurrences (all)	20		
Vomiting			
subjects affected / exposed	8 / 44 (18.18%)		
occurrences (all)	9		
Psychiatric disorders			

Anxiety subjects affected / exposed occurrences (all)	3 / 44 (6.82%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 May 2009	Update the list of investigators
29 September 2009	- Modification of the no inclusion criteria - Evaluation of the response to M6 and not to M3 - Extension of inclusion until 28/01/2014
20 December 2011	- Increased radiation therapy dose from 40 to 48 Gy - Extension of inclusion until December 2014
19 June 2012	- Update the list of investigator(s) - Update of the sponsor’s contact details
16 July 2013	- Update the list of investigator(s)
21 January 2014	- Extension of inclusion until 19/06/2014 - Increase the number of patient to include - Update the list of investigator(s)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported