Clinical trial results:
PHASE II RANDOMISEE EVALUANT L'EFFICACITE ET LA TOLERANCE DE 2 STRATEGIES THERAPEUTIQUES COMBINANT LE BEVACIZUMAB A LA CHIMIOTHERAPIE: DESESCALADE VERSUS ESCALADE CHEZ DES PATIENTS AYANT UN CANCER COLORECTAL METASTATIQUE NON RESECABLE ET NON PRE-TRAITE

Summary

EudraCT number	2016-001225-13
Trial protocol	FR
Global end of trial date	12 October 2020

Results information

Result version number	v1 (current)
This version publication date	06 July 2025
First version publication date	06 July 2025

Trial information

Trial identification

Sponsor protocol code	PRODIGE45

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02842580
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fédération Francophone de Cancérologie Digestive
Sponsor organisation address	7 bd Jeanne d'Arc, Dijon, France, 21000
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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	09 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 October 2020
Global end of trial reached?	Yes
Global end of trial date	12 October 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the failure rate of the strategy 16 months after randomization. Failure of the strategy was defined as: Progression (defined in each arm)* using RECIST v1.1 criteria or Death (all causes) or Toxicity leading to permanent discontinuation of one of the chemotherapy drugs (oxaliplatin and irinotecan) or Patient refusal to continue the strategy or Investigator's decision to discontinue the strategy.

Protection of trial subjects:

This trial was conducted in accordance with the New European Directive 2001/20/EC. The investigator undertook to obtain the patient's consent for the clinical and biological studies in writing, after providing adequate information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 September 2016
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: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	9
From 65 to 84 years	11

85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Between 15 Septembre 2016 and 10 April 2018, 21 patients were randomized by 9 french centers

Pre-assignment

Screening details:

After checking the inclusion and non-inclusion criteria, patients were randomized to the protocol. Main eligible criteria were histologically proven, non resectable mCRC, BRAF non mutated patients, WHO-OMS less of equal to 2, at least one measurable lesion according to RECIST 1.1 and able to receive the treatments

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A: escalation strategy

Arm description:

Patients started the strategy with a first chemotherapy regimen consisting of LV5FU2 (or capecitabine) + bevacizumab. After progression, they received a second chemotherapy regimen consisting of FOLFIRI + bevacizumab. After progression, they received a third chemotherapy regimen consisting of FOLFOX4 + bevacizumab.
When progression occured during the third chemotherapy or if the third chemotherapy was not administered, patients was treated according to the investigator's choice.
The duration of a chemotherapy cycle was 14 days or 21 days if the patient received capecitabine instead of LV5FU.

Arm type	Active comparator
Investigational medicinal product name	LV5FU2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

5FU bolus was administrated at 400 mg/m² (at D1).
5FU continu was administrated in IV at the dosage of 2400 mg/m² over 46 hour (D1 and D2).

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

Dosage and administration details:

Bevacizumab was administered intravenously before chemotherapy at a dose of 5 mg/kg over 90 minutes in cycle 1, then, if well tolerated, over 60 minutes in cycle 2 and over 30 minutes in subsequent cycles.

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

Dosage and administration details:

Irinotecan was administered intravenously at a dose of 180 mg/m² over 90 minutes.

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

Dosage and administration details:

Oxaliplatin was administered intravenously at a dose of 85 mg/m² over 120 minutes.

Arm title	Arm B: de-escalation strategy

Arm description:

Patients received 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, then maintenance treatment with capecitabine/LV5FU2 and bevacizumab until progression.
After progression during maintenance treatment, the patient was treated with 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, followed by maintenance treatment with capecitabine and bevacizumab until progression, etc. The duration of a chemotherapy cycle was 14 days for maintenance cycles with LV5FU2 and 21 days for maintenance cycles with capecitabine.

If progression occured during treatment with modified FOLFOXIRI + bevacizumab or FOLFIRI + bevacizumab, patients were considered to have failed the strategy and was treated according to the investigator's choice.

Arm type	Experimental
Investigational medicinal product name	LV5FU2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

5FU bolus was administrated at 400 mg/m² (at D1).
5FU continu was administrated in IV at the dosage of 2400 mg/m² over 46 hour (D1 and D2).

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

Dosage and administration details:

Bevacizumab was administered intravenously before chemotherapy at a dose of 5 mg/kg over 90 minutes in cycle 1, then, if well tolerated, over 60 minutes in cycle 2 and over 30 minutes in subsequent cycles.

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

Dosage and administration details:

Irinotecan was administered intravenously at a dose of 180 mg/m² over 90 minutes.

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

Dosage and administration details:

Oxaliplatin was administered intravenously at a dose of 85 mg/m² over 120 minutes.

Number of subjects in period 1	Arm A: escalation strategy	Arm B: de-escalation strategy
Started	11	10
Completed	11	10

Baseline characteristics

Reporting groups

Reporting group title	Arm A: escalation strategy

Reporting group description:

Patients started the strategy with a first chemotherapy regimen consisting of LV5FU2 (or capecitabine) + bevacizumab. After progression, they received a second chemotherapy regimen consisting of FOLFIRI + bevacizumab. After progression, they received a third chemotherapy regimen consisting of FOLFOX4 + bevacizumab.
When progression occured during the third chemotherapy or if the third chemotherapy was not administered, patients was treated according to the investigator's choice.
The duration of a chemotherapy cycle was 14 days or 21 days if the patient received capecitabine instead of LV5FU.

Reporting group title	Arm B: de-escalation strategy

Reporting group description:

Patients received 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, then maintenance treatment with capecitabine/LV5FU2 and bevacizumab until progression.
After progression during maintenance treatment, the patient was treated with 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, followed by maintenance treatment with capecitabine and bevacizumab until progression, etc. The duration of a chemotherapy cycle was 14 days for maintenance cycles with LV5FU2 and 21 days for maintenance cycles with capecitabine.

If progression occured during treatment with modified FOLFOXIRI + bevacizumab or FOLFIRI + bevacizumab, patients were considered to have failed the strategy and was treated according to the investigator's choice.

Reporting group values	Arm A: escalation strategy	Arm B: de-escalation strategy	Total
Number of subjects	11	10	21
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	5	9
From 65-84 years	7	4	11
85 years and over	0	1	1
Gender categorical Units: Subjects			
Female	4	2	6
Male	7	8	15

Subject analysis sets

Subject analysis set title	ITT set
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All patients randomizedin the study regardless of inclusion and exclusion criteria and analyzed according

to the strategy assigned by randomization.

Reporting group values	ITT set		
Number of subjects	21		
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)	9		
From 65-84 years	11		
85 years and over	1		
Gender categorical Units: Subjects			
Female	6		
Male	15		

End points

End points reporting groups

Reporting group title	Arm A: escalation strategy

Reporting group description:

Patients started the strategy with a first chemotherapy regimen consisting of LV5FU2 (or capecitabine) + bevacizumab. After progression, they received a second chemotherapy regimen consisting of FOLFIRI + bevacizumab. After progression, they received a third chemotherapy regimen consisting of FOLFOX4 + bevacizumab.
When progression occured during the third chemotherapy or if the third chemotherapy was not administered, patients was treated according to the investigator's choice.
The duration of a chemotherapy cycle was 14 days or 21 days if the patient received capecitabine instead of LV5FU.

Reporting group title	Arm B: de-escalation strategy

Reporting group description:

Patients received 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, then maintenance treatment with capecitabine/LV5FU2 and bevacizumab until progression.
After progression during maintenance treatment, the patient was treated with 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, followed by maintenance treatment with capecitabine and bevacizumab until progression, etc. The duration of a chemotherapy cycle was 14 days for maintenance cycles with LV5FU2 and 21 days for maintenance cycles with capecitabine.

If progression occured during treatment with modified FOLFOXIRI + bevacizumab or FOLFIRI + bevacizumab, patients were considered to have failed the strategy and was treated according to the investigator's choice.

Subject analysis set title	ITT set
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All patients randomizedin the study regardless of inclusion and exclusion criteria and analyzed according to the strategy assigned by randomization.

Primary: Rate of patients with strategy failure at 16 months

End point title	Rate of patients with strategy failure at 16 months[1]

End point description:

The failure rate of the strategy at 16 months after randomization was calculated based on the investigator's assessment at 16 months (+/- 30 days).
Failure of the strategy was defined by: 1/Progression (defined in each arm) using RECIST v1.1 criteria or 2/Death (all causes) or 3/Toxicity leading to permanent discontinuation of one of the chemotherapy products (oxaliplatin and irinotecan) or 4/ Patient refusal to continue the strategy or 5/Investigator's decision to discontinue the strategy.

End point type	Primary

End point timeframe:

16 months after the randomization

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 non-comparative study and was stopped prematurely at 21 patients. That's why no statistical analyses was done.

End point values	Arm A: escalation strategy	Arm B: de-escalation strategy	ITT set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	10	21	
Units: patients				
No strategy failure	7	4	11	

Strategy failure	4	6	10	

Statistical analyses

No statistical analyses for this end point

Secondary: Time until strategy failure

End point title	Time until strategy failure

End point description:

The time until strategy failure was the time between the randomization date and the date of the strategy failure

End point type	Secondary

End point timeframe:

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

End point values	Arm A: escalation strategy	Arm B: de-escalation strategy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: months				
median (inter-quartile range (Q1-Q3))	13.8 (10.1 to 15.8)	9.5 (3.9 to 13.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival

End point description:

Overall survival considered all deaths, and time was calculated from randomisation to death.

End point type	Secondary

End point timeframe:

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

End point values	Arm A: escalation strategy	Arm B: de-escalation strategy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: patients				
Death	6	5		
Alive	5	5		

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 signature of the informed consent form and until 30 days after the last dose of the study drug were reported by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	NCI-CTC
Dictionary version	4.0

Reporting groups

Reporting group title	Arm A: escalation strategy

Reporting group description:

Patients started the strategy with a first chemotherapy regimen consisting of LV5FU2 (or capecitabine) + bevacizumab. After progression, they received a second chemotherapy regimen consisting of FOLFIRI + bevacizumab. After progression, they received a third chemotherapy regimen consisting of FOLFOX4 + bevacizumab.
When progression occured during the third chemotherapy or if the third chemotherapy cannot be administered, patients was be treated according to the investigator's choice.
The duration of a chemotherapy cycle was14 days or 21 days if the patient received capecitabine.

Reporting group title	Arm B: de-escalation strategy

Reporting group description:

Patients received 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, then maintenance treatment with capecitabine/LV5FU2 and bevacizumab until progression.
After progression during maintenance treatment, the patient resumed treatment with 4 cycles of modified FOLFOXIRI + bevacizumab, followed by 4 cycles of FOLFIRI + bevacizumab, followed by maintenance treatment with capecitabine and bevacizumab until progression, etc. The duration of a chemotherapy cycle was 14 days for maintenance cycles with LV5FU2 and 21 days for maintenance cycles with capecitabine.

If progression occured during treatment with modified FOLFOXIRI + bevacizumab or FOLFIRI + bevacizumab, patients were considered to have failed the strategy and was treated according to the investigator's choice.

Serious adverse events	Arm A: escalation strategy	Arm B: de-escalation strategy	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 11 (36.36%)	0 / 10 (0.00%)	
number of deaths (all causes)	6	5	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Cardiac arrest			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Arm A: escalation strategy	Arm B: de-escalation strategy	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 11 (90.91%)	9 / 10 (90.00%)	
Vascular disorders			
Thromboembolic event			
subjects affected / exposed	0 / 11 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	8 / 11 (72.73%)	8 / 10 (80.00%)	
occurrences (all)	8	8	
Fever			

subjects affected / exposed	3 / 11 (27.27%)	2 / 10 (20.00%)	
occurrences (all)	3	2	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Epistaxis			
subjects affected / exposed	4 / 11 (36.36%)	2 / 10 (20.00%)	
occurrences (all)	4	2	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Insomnia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Investigations			
ALAT increase			
subjects affected / exposed	4 / 11 (36.36%)	4 / 10 (40.00%)	
occurrences (all)	4	4	
Anemia			
subjects affected / exposed	7 / 11 (63.64%)	8 / 10 (80.00%)	
occurrences (all)	7	8	
ASAT increase			
subjects affected / exposed	5 / 11 (45.45%)	2 / 10 (20.00%)	
occurrences (all)	5	2	
Bilirubin increase			
subjects affected / exposed	2 / 11 (18.18%)	2 / 10 (20.00%)	
occurrences (all)	2	2	
Creatinin increase			
subjects affected / exposed	3 / 11 (27.27%)	1 / 10 (10.00%)	
occurrences (all)	3	1	
GGT increase			
subjects affected / exposed	9 / 11 (81.82%)	6 / 10 (60.00%)	
occurrences (all)	9	6	
White blood cell decrease			

subjects affected / exposed	3 / 11 (27.27%)	3 / 10 (30.00%)	
occurrences (all)	3	3	
PNN decrease			
subjects affected / exposed	5 / 11 (45.45%)	0 / 10 (0.00%)	
occurrences (all)	5	0	
Decreased lymphocyte count			
subjects affected / exposed	2 / 11 (18.18%)	2 / 10 (20.00%)	
occurrences (all)	2	2	
Thrombopenia			
subjects affected / exposed	4 / 11 (36.36%)	2 / 10 (20.00%)	
occurrences (all)	4	2	
Cardiac disorders			
Arterial Hypertension			
subjects affected / exposed	2 / 11 (18.18%)	4 / 10 (40.00%)	
occurrences (all)	2	4	
Nervous system disorders			
Cephalgia			
subjects affected / exposed	2 / 11 (18.18%)	2 / 10 (20.00%)	
occurrences (all)	2	2	
Dysgeusia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Sensitive peripheral neuropathy			
subjects affected / exposed	6 / 11 (54.55%)	9 / 10 (90.00%)	
occurrences (all)	6	9	
Mucositis			
subjects affected / exposed	6 / 11 (54.55%)	5 / 10 (50.00%)	
occurrences (all)	6	5	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 11 (18.18%)	3 / 10 (30.00%)	
occurrences (all)	2	3	
Diarrhoea			

subjects affected / exposed	8 / 11 (72.73%)	7 / 10 (70.00%)	
occurrences (all)	8	7	
Abdominal pain			
subjects affected / exposed	1 / 11 (9.09%)	3 / 10 (30.00%)	
occurrences (all)	1	3	
Dyspepsia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Hemorrhoids			
subjects affected / exposed	2 / 11 (18.18%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Nausea			
subjects affected / exposed	9 / 11 (81.82%)	4 / 10 (40.00%)	
occurrences (all)	9	4	
Vomiting			
subjects affected / exposed	5 / 11 (45.45%)	3 / 10 (30.00%)	
occurrences (all)	5	3	
PAL increase			
subjects affected / exposed	8 / 11 (72.73%)	6 / 10 (60.00%)	
occurrences (all)	8	6	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	4 / 11 (36.36%)	2 / 10 (20.00%)	
occurrences (all)	4	2	
Dry skin			
subjects affected / exposed	2 / 11 (18.18%)	3 / 10 (30.00%)	
occurrences (all)	2	3	
Palmar erythrodysesthesia syndrome			
subjects affected / exposed	3 / 11 (27.27%)	5 / 10 (50.00%)	
occurrences (all)	3	5	
Renal and urinary disorders			
Hematuria			

subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Proteinuria			
subjects affected / exposed	4 / 11 (36.36%)	4 / 10 (40.00%)	
occurrences (all)	4	4	
Infections and infestations			
Cutaneous infection			
subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Urinary tractus infection			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	4 / 11 (36.36%)	2 / 10 (20.00%)	
occurrences (all)	4	2	
Hyperglycemia			
subjects affected / exposed	2 / 11 (18.18%)	3 / 10 (30.00%)	
occurrences (all)	2	3	
Hyperkaliemia			
subjects affected / exposed	5 / 11 (45.45%)	3 / 10 (30.00%)	
occurrences (all)	5	3	
Hypoalbuminemia			
subjects affected / exposed	3 / 11 (27.27%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
Hypophosphatemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	

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