Clinical trial results:
Nal-IRI/LV5-FU VERSUS PACLITAXEL AS SECOND-LINE THERAPY IN PATIENTS WITH METASTATIC OESOPHAGEAL SQUAMOUS CELL CARCINOMA

Summary

EudraCT number	2017-004730-28
Trial protocol	FR
Global end of trial date	30 September 2024

Results information

Result version number	v1 (current)
This version publication date	02 January 2026
First version publication date	02 January 2026

Trial information

Trial identification

Sponsor protocol code	PRODIGE 62

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03719924
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,
Public contact	Head of Biostatistics, Fédération Francophone de Cancérologie Digestive (FFCD), +33 380393483, karine.le-malicot@u-bourgogne.fr
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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	29 April 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 March 2024
Global end of trial reached?	Yes
Global end of trial date	30 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the survival of patients at 9 months

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	07 March 2019
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: 106
Worldwide total number of subjects	106
EEA total number of subjects	106

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)	51
From 65 to 84 years	55
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between March 7th, 2019 and July 5th, 2023, 106 patients in 43 centers were randomized (53 patients in each arm)

Pre-assignment

Screening details:

Main inclusion criteria were patients aged 18 years or older, histologically proven mESCC, with progression or intolerance after 1st line platinum-based CT. Patients with resectable disease treated with surgery and pre- or post-operative CT could be included if a metastatic recurrence occurred within 6 month after end of treatment

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Bras A - Nal-IRI plus LV5FU

Arm description:

Patients received the 5FU Nal-IRI regimen with folinic acid 400 mg/ m2 in a 2-hour intravenous (IV) infusion, continuous 5FU 2400 mg/m2 in a 46-hour IV infusion and nal-iri at 70 mg/m² in a 2-hour IV infusion, every 14 days.

Arm type	Experimental
Investigational medicinal product name	5FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

continuous 5FU 2400 mg/m2 in a 46-hour IV infusion every 14 days

Investigational medicinal product name	Nal-Iri
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

nal-iri at 70 mg/m² in a 2-hour IV infusion, every 14 days

Arm title	Bras B - Paclitaxel

Arm description:

In the control arm, paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle

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

Dosage and administration details:

Paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle

Number of subjects in period 1	Bras A - Nal-IRI plus LV5FU	Bras B - Paclitaxel
Started	53	53
Completed	50	51
Not completed	3	2
Not treatedreated	-	2
Not treated	3	-

Period 2

Period 2 title	Treatment period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Bras A - Nal-IRI plus LV5FU

Arm description:

Patients received the 5FU Nal-IRI regimen with folinic acid 400 mg/ m2 in a 2-hour intravenous (IV) infusion, continuous 5FU 2400 mg/m2 in a 46-hour IV infusion and nal-iri at 70 mg/m² in a 2-hour IV infusion, every 14 days.

Arm type	Experimental
Investigational medicinal product name	5FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

continuous 5FU 2400 mg/m2 in a 46-hour IV infusion every 14 days

Investigational medicinal product name	Nal-Iri
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

nal-iri at 70 mg/m² in a 2-hour IV infusion, every 14 days

Investigational medicinal product name	5FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

continuous 5FU 2400 mg/m2 in a 46-hour IV infusion every 14 days

Arm title	Bras B - Paclitaxel

Arm description:

In the control arm, paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle

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

Dosage and administration details:

Paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle

Number of subjects in period 2	Bras A - Nal-IRI plus LV5FU	Bras B - Paclitaxel
Started	50	51
Completed	50	51

Period 3

Period 3 title	Safety Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Bras A - Nal-IRI plus LV5FU/5FU

Arm description: -

Arm type	Experimental
Investigational medicinal product name	5FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

continuous 5FU 2400 mg/m2 in a 46-hour IV infusion every 14 days

Arm title	Bras B - Paclitaxel
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle

Number of subjects in period 3	Bras A - Nal-IRI plus LV5FU/5FU	Bras B - Paclitaxel
Started	49	52
Completed	49	52

Baseline characteristics

Reporting groups

Reporting group title	Bras A - Nal-IRI plus LV5FU

Reporting group description:

Patients received the 5FU Nal-IRI regimen with folinic acid 400 mg/ m2 in a 2-hour intravenous (IV) infusion, continuous 5FU 2400 mg/m2 in a 46-hour IV infusion and nal-iri at 70 mg/m² in a 2-hour IV infusion, every 14 days.

Reporting group title	Bras B - Paclitaxel

Reporting group description:

In the control arm, paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle

Reporting group values	Bras A - Nal-IRI plus LV5FU	Bras B - Paclitaxel	Total
Number of subjects	53	53	106
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)	25	26	51
From 65-84 years	28	27	55
85 years and over	0	0	0
Age continuous Units: years			
median	66.8	65.1	
inter-quartile range (Q1-Q3)	60.6 to 71.7	59.7 to 70.4	-
Gender categorical Units: Subjects			
Female	7	11	18
Male	46	42	88

Subject analysis sets

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

Subject analysis set description:

Analyses of primary and secondary efficacy endpoints were conducted on the modified intention-to-treat population (mITT population), i.e. all patients who had received at least one dose of treatment in the study, regardless of their eligibility criteria

Subject analysis set title	Safety set
Subject analysis set type	Safety analysis

Subject analysis set description:

Safety analyses were conducted on all patients receiving at least one dose of treatment and according to the treatment received

Reporting group values	mITT set	Safety set	
Number of subjects	101	101	
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)	48	48	
From 65-84 years	53	53	
85 years and over	0	0	
Age continuous Units: years			
median	66	66	
inter-quartile range (Q1-Q3)	60 to 71.2	60 to 71.2	
Gender categorical Units: Subjects			
Female	18	18	
Male	83	83	

End points

End points reporting groups

Reporting group title	Bras A - Nal-IRI plus LV5FU
Reporting group description:	
Patients received the 5FU Nal-IRI regimen with folinic acid 400 mg/ m2 in a 2-hour intravenous (IV) infusion, continuous 5FU 2400 mg/m2 in a 46-hour IV infusion and nal-iri at 70 mg/m² in a 2-hour IV infusion, every 14 days.	
Reporting group title	Bras B - Paclitaxel
Reporting group description:	
In the control arm, paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle	
Reporting group title	Bras A - Nal-IRI plus LV5FU
Reporting group description:	
Patients received the 5FU Nal-IRI regimen with folinic acid 400 mg/ m2 in a 2-hour intravenous (IV) infusion, continuous 5FU 2400 mg/m2 in a 46-hour IV infusion and nal-iri at 70 mg/m² in a 2-hour IV infusion, every 14 days.	
Reporting group title	Bras B - Paclitaxel
Reporting group description:	
In the control arm, paclitaxel was administered at a dose of 80 mg/m2 at day 1, day 8 and day 14 of a 28-day cycle	
Reporting group title	Bras A - Nal-IRI plus LV5FU/5FU
Reporting group description: -	
Reporting group title	Bras B - Paclitaxel
Reporting group description: -	
Subject analysis set title	mITT set
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Analyses of primary and secondary efficacy endpoints were conducted on the modified intention-to-treat population (mITT population), i.e. all patients who had received at least one dose of treatment in the study, regardless of their eligibility criteria	
Subject analysis set title	Safety set
Subject analysis set type	Safety analysis
Subject analysis set description:	
Safety analyses were conducted on all patients receiving at least one dose of treatment and according to the treatment received	

Primary: Rate of patients alive 9 months after randomisation[

End point title	Rate of patients alive 9 months after randomisation[[1]]
End point description:	
The primary endpoint was defined as the rate of patients alive 9-month after randomization. This rate of patients alive at 9 months was assessed based on the time between the patient's randomization date and the date of death (regardless of the cause). Alive patients were censored at the date of their last news.	
End point type	Primary
End point timeframe:	
9 months after 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 that's why no statistical analysis was done.

End point values	Bras A - Nal-IRI plus LV5FU	Bras B - Paclitaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	51		
Units: patients				
Patients alive at 9 months	17	20		
Patients dead at 9 months	33	31		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)

End point description:

The progression-free-survival was defined as the time from the randomization to the first clinical/radiological progression (according to RECIST 1.1 criteria) or the date of the death from any cause. Patient alive were censored at the date of the last news.

End point type	Secondary

End point timeframe:

6 months after randomization

End point values	Bras A - Nal-IRI plus LV5FU	Bras B - Paclitaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	51		
Units: months				
median (inter-quartile range (Q1-Q3))	2.4 (2.1 to 3.6)	2.1 (1.9 to 3.3)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected before each cycle of chemotherapy systematically during the whole protocol of treatment

Assessment type	Systematic

Dictionary used

Dictionary name	NCI-CTC
Dictionary version	4.0

Reporting groups

Reporting group title	Bras A - Nal-IRI plus LV5FU
Reporting group description: -	
Reporting group title	Bras B - Paclitaxel

Reporting group description: -

Serious adverse events	Bras A - Nal-IRI plus LV5FU	Bras B - Paclitaxel	
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 49 (53.06%)	15 / 52 (28.85%)	
number of deaths (all causes)	33	31	
number of deaths resulting from adverse events	5	4	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight loss			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Thromboembolic event			
subjects affected / exposed	2 / 49 (4.08%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sinusal Tachycardia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	2 / 49 (4.08%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac Thoracic pain			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	4 / 49 (8.16%)	6 / 52 (11.54%)	
occurrences causally related to treatment / all	2 / 4	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
Fever			

subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Discomfort			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 49 (10.20%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	4 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal pain			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	1 / 49 (2.04%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomach pain			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	2 / 49 (4.08%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Gastro-intestinal hemorraghe			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Inflammation of the lining of the small intestine			

subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 49 (4.08%)	2 / 52 (3.85%)	
occurrences causally related to treatment / all	2 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Voice alteration			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	2 / 49 (4.08%)	3 / 52 (5.77%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonite			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	2 / 49 (4.08%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Enterocolitis infectious			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma site infection			
subjects affected / exposed	0 / 49 (0.00%)	2 / 52 (3.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
subjects affected / exposed	1 / 49 (2.04%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone infection			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary infection			
subjects affected / exposed	3 / 49 (6.12%)	3 / 52 (5.77%)	
occurrences causally related to treatment / all	1 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	2 / 49 (4.08%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hyponatremia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Bras A - Nal-IRI plus LV5FU	Bras B - Paclitaxel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 49 (97.96%)	51 / 52 (98.08%)	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	10 / 49 (20.41%)	14 / 52 (26.92%)	
occurrences (all)	10	14	
Bilirubin increased			
subjects affected / exposed	2 / 49 (4.08%)	5 / 52 (9.62%)	
occurrences (all)	2	5	
Gamma-glutamyltransferase increased			
subjects affected / exposed	15 / 49 (30.61%)	18 / 52 (34.62%)	
occurrences (all)	15	18	
White blood cell count decreased			
subjects affected / exposed	15 / 49 (30.61%)	17 / 52 (32.69%)	
occurrences (all)	15	17	
Lymphocytes decreased			
subjects affected / exposed	8 / 49 (16.33%)	21 / 52 (40.38%)	
occurrences (all)	8	21	
Weight loss			
subjects affected / exposed	6 / 49 (12.24%)	3 / 52 (5.77%)	
occurrences (all)	6	3	
Phosphatases alcalines increased			
subjects affected / exposed	8 / 49 (16.33%)	16 / 52 (30.77%)	
occurrences (all)	8	16	
Platelets decreased			
subjects affected / exposed	8 / 49 (16.33%)	9 / 52 (17.31%)	
occurrences (all)	8	9	

Nervous system disorders			
Dysgueusia			
subjects affected / exposed	5 / 49 (10.20%)	3 / 52 (5.77%)	
occurrences (all)	5	3	
Neuropathy peripheral sensitive			
subjects affected / exposed	16 / 49 (32.65%)	25 / 52 (48.08%)	
occurrences (all)	16	25	
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	29 / 49 (59.18%)	36 / 52 (69.23%)	
occurrences (all)	29	36	
General disorders and administration site conditions			
Non cardiac thoracic pain			
subjects affected / exposed	2 / 49 (4.08%)	3 / 52 (5.77%)	
occurrences (all)	2	3	
Fatigue			
subjects affected / exposed	29 / 49 (59.18%)	35 / 52 (67.31%)	
occurrences (all)	29	35	
Fever			
subjects affected / exposed	5 / 49 (10.20%)	6 / 52 (11.54%)	
occurrences (all)	5	6	
Limb edema			
subjects affected / exposed	1 / 49 (2.04%)	4 / 52 (7.69%)	
occurrences (all)	1	4	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	6 / 49 (12.24%)	7 / 52 (13.46%)	
occurrences (all)	6	7	
Diarrhoea			
subjects affected / exposed	34 / 49 (69.39%)	17 / 52 (32.69%)	
occurrences (all)	34	17	
Abdominal pain			
subjects affected / exposed	9 / 49 (18.37%)	1 / 52 (1.92%)	
occurrences (all)	9	1	
Stomach pain			

subjects affected / exposed	1 / 49 (2.04%)	6 / 52 (11.54%)	
occurrences (all)	1	6	
Dysphagia			
subjects affected / exposed	8 / 49 (16.33%)	12 / 52 (23.08%)	
occurrences (all)	8	12	
Mucositis			
subjects affected / exposed	9 / 49 (18.37%)	9 / 52 (17.31%)	
occurrences (all)	9	9	
Nausea			
subjects affected / exposed	24 / 49 (48.98%)	16 / 52 (30.77%)	
occurrences (all)	24	16	
Vomiting			
subjects affected / exposed	13 / 49 (26.53%)	9 / 52 (17.31%)	
occurrences (all)	13	9	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	9 / 49 (18.37%)	9 / 52 (17.31%)	
occurrences (all)	9	9	
Cough			
subjects affected / exposed	5 / 49 (10.20%)	8 / 52 (15.38%)	
occurrences (all)	5	8	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 49 (4.08%)	3 / 52 (5.77%)	
occurrences (all)	2	3	
Musculoskeletal and connective tissue disorders			
Dorsalgia			
subjects affected / exposed	2 / 49 (4.08%)	5 / 52 (9.62%)	
occurrences (all)	2	5	
Myalgia			
subjects affected / exposed	2 / 49 (4.08%)	4 / 52 (7.69%)	
occurrences (all)	2	4	
Infections and infestations			
Bronchial infection			
subjects affected / exposed	2 / 49 (4.08%)	3 / 52 (5.77%)	
occurrences (all)	2	3	

Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	18 / 49 (36.73%)	10 / 52 (19.23%)	
occurrences (all)	18	10	
Hyperkaliemia			
subjects affected / exposed	4 / 49 (8.16%)	5 / 52 (9.62%)	
occurrences (all)	4	5	
Hypoalbuminemia			
subjects affected / exposed	6 / 49 (12.24%)	7 / 52 (13.46%)	
occurrences (all)	6	7	
Hypocalcemia			
subjects affected / exposed	4 / 49 (8.16%)	3 / 52 (5.77%)	
occurrences (all)	4	3	
Hyponatremia			
subjects affected / exposed	5 / 49 (10.20%)	3 / 52 (5.77%)	
occurrences (all)	5	3	

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/4087608