Clinical trial results:
Etude de phase II randomisée ouverte non comparative multicentrique de l'évaluation de l'erlotinib séquentiel associé au docetaxel versus docetaxel seul en deuxième ligne de traitement chez des patients présentant un cancer bronchique non petites cellules stade IV en progression

Summary

EudraCT number	2010-024592-77
Trial protocol	FR
Global end of trial date	18 March 2013

Results information

Result version number	v1 (current)
This version publication date	20 June 2021
First version publication date	20 June 2021
Summary attachment (see zip file)	Publication (TARSEQ_GFPC 10.02 _publication.pdf)

Trial information

Trial identification

Sponsor protocol code	I10004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01350817
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU de Limoges
Sponsor organisation address	2 AV Martin Luther King, Limoges, France, 87042
Public contact	Alain Vergnenegre, CHU de Limoges, 33 555056629, alain.vergnegre@unilim.fr
Scientific contact	Alain Vergnenegre, CHU de Limoges, 33 555056629, alain.vergnegre@unilim.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	15 November 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 March 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of the association docetaxel with sequential erlotinib in term of percentage of progression free survival at 15 weeks after disease progression

Protection of trial subjects:

The trial was conduted according to o all applicable Regulations, GCP guidelines, and IRB/EC requirements.
Subject were appropriately informed and an informed consent was obtained prior to conducting any study procedures. We perform a thorough review of each informed consent form that every subject signs, as well as any other documentation about the informed consent process; we do this to ensure that the consent was obtained properly, according to all applicable Regulations, GCP guidelines, and IRB/EC requirements.
A IDMC has been established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 June 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 151
Worldwide total number of subjects	151
EEA total number of subjects	151

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)	110
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

156 patients included in 33 French centers between June 2011 and February 2013.

Pre-assignment

Screening details:

Patients aged 18 years or more, perfor-mance status (PS) 0, 1 or 2, cytologically or histologically provenstage IV or IIIB NSCLC with T4 staging by neoplastic pleural effu-sion, already treated with first-line cisplatin-based chemotherapy,with wild-type or unknown EGFR status,

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Erlotinib + docetaxel

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Erlotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

150 mg/day per os form Day 2 to Day 16 for each cycle

Arm title	Docetaxel

Arm description: -

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

Dosage and administration details:

75 mg/m² IV à D1 de chaque cycle (every 3 week)

Number of subjects in period 1	Erlotinib + docetaxel	Docetaxel
Started	75	76
Completed	73	74
Not completed	2	2
Consent withdrawn by subject	2	2

Baseline characteristics

Reporting groups	
Reporting group title	Erlotinib + docetaxel
Reporting group description: -	
Reporting group title	Docetaxel
Reporting group description: -	

Reporting group values	Erlotinib + docetaxel	Docetaxel	Total
Number of subjects	75	76	151
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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	59.39	59.6	
full range (min-max)	37 to 75	44 to 75	-
Gender categorical Units: Subjects			
Female	14	21	35
Male	61	55	116

End points

End points reporting groups

Reporting group title	Erlotinib + docetaxel
Reporting group description: -	
Reporting group title	Docetaxel
Reporting group description: -	

Primary: Progression-free survival (PFS)

End point title	Progression-free survival (PFS)[1]
End point description:	
End point type	Primary
End point timeframe:	
At 15 weeks	

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: No statistical analyses available

End point values	Erlotinib + docetaxel	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	74		
Units: Month				
median (confidence interval 95%)	2.2 (1.5 to 2.7)	2.5 (1.6 to 2.8)		

Attachments (see zip file)	kaplan-Meir curve/Kapla-Meir curve.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival
End point description:	
End point type	Secondary
End point timeframe:	
At 12 months	

End point values	Erlotinib + docetaxel	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	74		
Units: Month				
median (confidence interval 95%)	6.5 (4.43 to 10.1)	8.3 (4.5 to 11.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: One-yearsurvival rate

End point title	One-yearsurvival rate

End point description:

End point type	Secondary

End point timeframe:

At 12 months

End point values	Erlotinib + docetaxel	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	73	74		
Units: Percentage				
number (confidence interval 95%)	35.6 (24.9 to 46.5)	37.8 (26.9 to 48.7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From the inclusion up to one month after the end of the treatment	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	Erlotinib+Decetaxel
Reporting group description: -	
Reporting group title	Docetaxel
Reporting group description: -	

Serious adverse events	Erlotinib+Decetaxel	Docetaxel	
Total subjects affected by serious adverse events			
subjects affected / exposed	48 / 73 (65.75%)	34 / 74 (45.95%)	
number of deaths (all causes)	24	12	
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to adrenals			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic pain			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Neoplasm progression			
subjects affected / exposed	2 / 73 (2.74%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 73 (1.37%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Brain tumour operation			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device change			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (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			
Asthenia			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			

subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	12 / 73 (16.44%)	10 / 74 (13.51%)	
occurrences causally related to treatment / all	4 / 12	1 / 10	
deaths causally related to treatment / all	4 / 10	1 / 5	
Hyperthermia			
subjects affected / exposed	3 / 73 (4.11%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 73 (0.00%)	3 / 74 (4.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	2 / 73 (2.74%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Dyspnoea			

subjects affected / exposed	3 / 73 (4.11%)	7 / 74 (9.46%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 1	
Epistaxis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	2 / 73 (2.74%)	3 / 74 (4.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hydropneumothorax			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	2 / 73 (2.74%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumonia			

subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	2 / 73 (2.74%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Respiratory distress			
subjects affected / exposed	1 / 73 (1.37%)	3 / 74 (4.05%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 1	1 / 3	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 73 (0.00%)	2 / 74 (2.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Ejection fraction decreased			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 73 (1.37%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Femur fracture			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation oesophagitis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Axonal neuropathy			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar syndrome			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	2 / 73 (2.74%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic hyperosmolar coma			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Grand mal convulsion			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 73 (4.11%)	2 / 74 (2.70%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow failure			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile bone marrow aplasia			
subjects affected / exposed	2 / 73 (2.74%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	5 / 73 (6.85%)	2 / 74 (2.70%)	
occurrences causally related to treatment / all	4 / 5	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	2 / 73 (2.74%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paratracheal lymphadenopathy			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Anal fistula			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	2 / 73 (2.74%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 73 (1.37%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			

subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 73 (2.74%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	0 / 73 (0.00%)	2 / 74 (2.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile bone marrow aplasia			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 73 (1.37%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Pathological fracture			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Dev ice related infection			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Dev ice related sepsis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Furuncle			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inf ection			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung inf ection			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Sepsis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 73 (0.00%)	2 / 74 (2.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 73 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 73 (1.37%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

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

Non-serious adverse events	Erlotinib+Decetaxel	Docetaxel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 73 (65.75%)	44 / 74 (59.46%)	
Investigations			
Neutrophile Count Decreased			
subjects affected / exposed	22 / 73 (30.14%)	19 / 74 (25.68%)	
occurrences (all)	44	58	
White Blood Cell Decreased			
subjects affected / exposed	8 / 73 (10.96%)	3 / 74 (4.05%)	
occurrences (all)	10	19	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	33 / 73 (45.21%)	28 / 74 (37.84%)	
occurrences (all)	40	31	
Gastrointestinal disorders			

Diarrhea			
subjects affected / exposed	25 / 73 (34.25%)	11 / 74 (14.86%)	
occurrences (all)	27	12	
Respiratory, thoracic and mediastinal disorders			
Dyspnea			
subjects affected / exposed	12 / 73 (16.44%)	14 / 74 (18.92%)	
occurrences (all)	14	15	

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