Clinical trial results:
A phase III, randomized, controlled, open-label, multicenter, global study of capmatinib versus SoC docetaxel chemotherapy in previously treated patients with EGFR wt, ALK negative, locally advanced or metastatic (stage IIIB/IIIC or IV) NSCLC harboring MET exon 14 skipping mutation (METex14).

Summary

EudraCT number	2020-001578-31
Trial protocol	HU NL DE PT FR LT BE IT BG
Global end of trial date	06 November 2023

Results information

Result version number	v1
This version publication date	06 October 2024
First version publication date	06 October 2024

Trial information

Trial identification

Sponsor protocol code	CINC280A2301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04427072
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Novartis Pharma AG , Clinical Disclosure Office, 41 613241111, Novartis.email@novartis.com
Scientific contact	Novartis Pharma AG , Clinical Disclosure Office, 41 613241111, Novartis.email@novartis.com

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	06 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 November 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial was to compare the efficacy of capmatinib versus docetaxel. Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 September 2020
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	Belgium: 1
Country: Number of subjects enrolled	Brazil: 1
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	India: 3
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Korea, Republic of: 1
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Portugal: 1
Country: Number of subjects enrolled	Spain: 6
Worldwide total number of subjects	22
EEA total number of subjects	17

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)	7
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All inclusion and exclusion criteria were checked at screening.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Capmatinib

Arm description:

400 mg, capmatinib tablets, administered orally twice daily

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

Dosage and administration details:

400 mg, capmatinib tablets, administered orally twice daily

Arm title	Docetaxel

Arm description:

Docetaxel 75 mg/m^2 solution administered by intravenous infusion on Day 1 of every 21-day cycle

Arm type	Active comparator
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Docetaxel 75 mg/m^2 by intravenous infusion every 21 days

Number of subjects in period 1	Capmatinib	Docetaxel
Started	15	7
Treated	15	6
Completed	0	0
Not completed	15	7
Adverse event, serious fatal	-	1
Adverse event, non-fatal	3	1

Study terminated by sponsor	3	-
Progressive disease	9	4
Not treated (participant decision)	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Capmatinib
Reporting group description:	
400 mg, capmatinib tablets, administered orally twice daily	
Reporting group title	Docetaxel
Reporting group description:	
Docetaxel 75 mg/m^2 solution administered by intravenous infusion on Day 1 of every 21-day cycle	

Reporting group values	Capmatinib	Docetaxel	Total
Number of subjects	15	7	22
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)	5	2	7
From 65-84 years	10	5	15
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	67.6	65.1	
standard deviation	± 9.26	± 4.98	-
Sex: Female, Male Units: participants			
Female	8	3	11
Male	7	4	11
Race/Ethnicity, Customized Units: Subjects			
White	11	6	17
Asian	3	0	3
Unknown	1	1	2

End points

End points reporting groups

Reporting group title	Capmatinib
Reporting group description:	
400 mg, capmatinib tablets, administered orally twice daily	
Reporting group title	Docetaxel
Reporting group description:	
Docetaxel 75 mg/m^2 solution administered by intravenous infusion on Day 1 of every 21-day cycle	

Primary: Progression-free Survival (PFS) per Blinded Independent Review Committee (BIRC) Using RECIST v1.1

End point title	Progression-free Survival (PFS) per Blinded Independent Review Committee (BIRC) Using RECIST v1.1[1]
End point description:	
Progression-free survival was defined as the time from the date of randomization to the date of the first documented progressive disease (PD) as assessed by BIRC according to RECIST 1.1, or death due to any cause. PD=At least a 20% increase in the sum of diameter of all measured target lesions, taking as reference the smallest sum of diameter of all target lesions recorded at or after baseline. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm^2. PFS was censored at the date of the last adequate tumor assessment, if no PFS event was observed prior to the analysis cut-off date.	
End point type	Primary
End point timeframe:	
From randomization to the date of first documented progression or death from any cause, whichever came first, assessed up to approximately 21 months	

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: Descriptive statistics are reported.

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: months				
median (confidence interval 95%)	6.1 (1.61 to 13.77)	4.1 (1.22 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response (ORR) per RECIST 1.1 by BIRC

End point title	Overall Response (ORR) per RECIST 1.1 by BIRC
End point description:	
Percentage of participants with confirmed best overall response (BOR) of complete response (CR) or partial response (PR), assessed by BIRC according to RECIST 1.1. CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.	

End point type	Secondary

End point timeframe:

Up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: percentage of participants				
number (confidence interval 95%)	53.3 (26.59 to 78.73)	0 (0 to 40.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response (TTR) per RECIST 1.1 by BIRC

End point title	Time to Response (TTR) per RECIST 1.1 by BIRC

End point description:

Time from date of randomization to first documented response of either CR or PR, which must be subsequently confirmed, assessed by BIRC according to RECIST 1.1. CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Secondary

End point timeframe:

From date of randomization to first documented response of either CR or PR, assessed up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	0[2]		
Units: months				
median (confidence interval 95%)	15.3 (1.74 to 999)	(to)		

Notes:

[2] - Data are reported for responders only.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response (TTR) per RECIST 1.1 by Investigator

End point title	Time to Response (TTR) per RECIST 1.1 by Investigator

End point description:

Time from date of randomization to first documented response of either CR or PR, which must be subsequently confirmed, assessed by local review according to RECIST 1.1. CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Secondary

End point timeframe:

From date of randomization to first documented response of either CR or PR, assessed up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	1		
Units: months				
median (confidence interval 95%)	999 (1.28 to 999)	999 (2.76 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) per RECIST 1.1 by Investigator

End point title	Overall Response Rate (ORR) per RECIST 1.1 by Investigator

End point description:

Percentage of participants with confirmed BOR of CR or PR, assessed by local review according to RECIST 1.1. CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Secondary

End point timeframe:

Up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: percentage of participants				
number (confidence interval 95%)	46.7 (21.27 to 73.41)	14.3 (0.36 to 57.87)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) per RECIST 1.1 by Investigator

End point title	Duration of Response (DOR) per RECIST 1.1 by Investigator

End point description:

Duration of response was defined as the time from the date of first documented response (CR or PR) to the first documented progression by local review per RECIST 1.1 or death due to any cause. CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Secondary

End point timeframe:

From first documented response to first documented progression or death due to any cause, whichever came first, assessed up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	1		
Units: months				
median (confidence interval 95%)	9.9 (2.92 to 999)	3.1 (0.999 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) per RECIST 1.1 by BIRC

End point title	Duration of Response (DOR) per RECIST 1.1 by BIRC

End point description:

Duration of response was defined as the time from the date of first documented response (CR or PR) to the first documented progression by BIRC per RECIST 1.1 or death due to any cause. CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Secondary

End point timeframe:

From first documented response to first documented progression or death due to any cause, whichever came first, assessed up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	0[3]		
Units: months				
median (confidence interval 95%)	12.6 (2.92 to 999)	(to)		

Notes:

[3] - Data are reported for responders only.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) per Investigator Using RECIST v1.1

End point title	Progression-free Survival (PFS) per Investigator Using RECIST v1.1

End point description:

Progression-free survival was defined as the time from the date of randomization to the date of the first documented progressive disease (PD) as assessed by local review according to RECIST 1.1, or death due to any cause. PD=At least a 20% increase in the sum of diameter of all measured target lesions, taking as reference the smallest sum of diameter of all target lesions recorded at or after baseline. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm^2.

End point type	Secondary

End point timeframe:

From randomization to the date of first documented progression or death from any cause, whichever came first, assessed up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: months				
median (confidence interval 95%)	6.1 (2.66 to 11.10)	3.6 (1.22 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR) per RECIST 1.1 by BIRC

End point title	Disease Control Rate (DCR) per RECIST 1.1 by BIRC

End point description:

Disease control rate was defined as the percentage of participants with a best overall response (BOR) of confirmed CR, PR and stable disease (SD) assessed by BIRC according to RECIST 1.1.
CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters; SD=Neither sufficient shrinkage to qualify for PR or CR nor an increase in lesions which would qualify for progressive disease.

End point type	Secondary

End point timeframe:

Up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: percentage of participants				
number (confidence interval 95%)	73.3 (44.90 to 92.21)	57.1 (18.41 to 90.10)		

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR) per RECIST 1.1 by Investigator

End point title	Disease Control Rate (DCR) per RECIST 1.1 by Investigator

End point description:

Disease control rate was defined as the percentage of participants with a best overall response (BOR) of confirmed CR, PR and stable disease (SD) assessed by local review according to RECIST 1.1. CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters; SD=Neither sufficient shrinkage to qualify for PR or CR nor an increase in lesions which would qualify for progressive disease.

End point type	Secondary

End point timeframe:

Up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: percentage of participants				
number (confidence interval 95%)	86.7 (59.54 to 98.34)	42.9 (9.90 to 81.59)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Intracranial Response Rate (OIRR)

End point title	Overall Intracranial Response Rate (OIRR)

End point description:

Percentage of participants with confirmed best overall intracranial response (BOIR) of CR or partial response (PR), as assessed by BIRC review per Response Assessment in Neuro-Oncology Brain Metastases (RANO-BM) criteria. Criteria for CR: Disappearance of all central nervous system (CNS)

target and non-target lesions sustained for at least 4 weeks, with no new lesions, and no use of corticosteroids. PR: ≥30% decrease in the sublaterodorsal tegmental nucleus (SLD) of CNS target lesions or no new lesions or and stable to decreased corticosteroid dose.

End point type	Secondary

End point timeframe:

Up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[4]		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.00 to 97.50)	(to)		

Notes:

[4] - Data are reported for responders only.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS was defined as the time from the date of randomization to the date of death due to any cause.

End point type	Secondary

End point timeframe:

From randomization to death due to any cause, assessed up to approximately 42 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: months				
median (confidence interval 95%)	12.5 (4.30 to 999)	13.6 (2.60 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Intracranial Response (DOIR)

End point title	Duration of Intracranial Response (DOIR)

End point description:

Time from date of first documented intracranial response (CR or PR) to first documented intracranial progression per RANO-BM assessed by BIRC or date of death due to underlying cause of cancer.

End point type	Secondary

End point timeframe:

From date of first documented intracranial response (CR or PR) to first documented intracranial progression, assessed up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[5]	0[6]		
Units: months				
median (confidence interval 95%)	(to)	(to)		

Notes:

[5] - DOIR could not be analyzed as there were no participants with intracranial response.

[6] - DOIR could not be analyzed as there were no participants with intracranial response.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Intracranial Response (TTIR)

End point title	Time to Intracranial Response (TTIR)

End point description:

Time from date of randomization to first documented intracranial response of either CR or PR, per RANO-BM criteria and assessed by BIRC, which must be subsequently confirmed.

End point type	Secondary

End point timeframe:

From date of randomization to first documented intracranial response of either CR or PR, assessed up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[7]	0[8]		
Units: months				
median (confidence interval 95%)	(to)	(to)		

Notes:

[7] - TTIR could not be analyzed as there were no participants with intracranial response.

[8] - TTIR could not be analyzed as there were no participants with intracranial response.

Statistical analyses

No statistical analyses for this end point

Secondary: Intracranial Disease Control Rate (IDCR)

End point title	Intracranial Disease Control Rate (IDCR)

End point description:

Percentage of participants with a BOR of confirmed CR, PR and stable disease (SD) (or non-CR/non-PD) per RANO-BM, assessed by BIRC. Criteria for CR: Disappearance of all central nervous system (CNS) target and non-target lesions sustained for at least 4 weeks, with no new lesions, and no use of corticosteroids. PR: ≥30% decrease in the sublaterodorsal tegmental nucleus (SLD) of CNS target

lesions or no new lesions or and stable to decreased corticosteroid dose.

End point type	Secondary

End point timeframe:

Up to approximately 21 months

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[9]		
Units: percentage of participants				
number (confidence interval 95%)	100 (2.50 to 100)	(to)		

Notes:

[9] - Not applicable to this reporting group.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Capmatinib Concentration

End point title	Plasma Capmatinib Concentration[10]

End point description:

Plasma concentrations of capmatinib. Blood samples were collected at indicated time points for pharmacokinetic analysis.

End point type	Secondary

End point timeframe:

Cycle (C) 1 Day (D) 15 pre-dose, 1 and 4 hours post-dose, C3 D1 pre-dose. Each cycle duration was 21 days.

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only applicable for participants who received capmatinib.

End point values	Capmatinib			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 15, 0 hour n=12	496 (± 97.3)			
Cycle 1, Day 15, 1 hour n=10	1330 (± 214.6)			
Cycle 1, Day 15, 4 hours n=11	2680 (± 131.1)			
Cycle 3, Day 1, 0 hour n=10	243 (± 140.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Score as per European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30

End point title	Change from Baseline in Score as per European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30

End point description:

EORTC-QLQ-C30 is a 30-item questionnaire developed to assess the quality of life of cancer patients. The questionnaire is composed of both multi-item scales and single-item measures based on the participants experience over the past week. These include five domains (physical, role, emotional, cognitive and social functioning), three symptom scales (fatigue, nausea/vomiting, and pain), six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial impact) and a global health status/HRQoL scale. All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level. CFB = change from baseline.

End point type	Secondary

End point timeframe:

Baseline, Cycle (C) 3, Day (D) 1 and then every 6 weeks up to approximately 21 months, end of treatment, and 6, 12, and 18 weeks post treatment. Each cycle duration was 21 days.

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: score on a scale				
arithmetic mean (standard deviation)				
Global Health Status CFB at Cycle 3, Day 1 n=12,4	17.4 (± 18.96)	4.2 (± 14.43)		
Global Health Status CFB at Cycle 5, Day n=8,3	14.6 (± 22.16)	8.3 (± 14.43)		
Global Health Status CFB at Cycle 7, Day 1 n=8,1	15.6 (± 16.33)	-8.3 (± 999)		
Global Health Status CFB at Cycle 9, Day 1 n=7,2	9.5 (± 16.96)	0.0 (± 11.79)		
Global Health Status CFB at Cycle 11, Day 1 n=7,0	3.6 (± 15.85)	999 (± 999)		
Global Health Status CFB at Cycle 13, Day 1 n=5,0	25.0 (± 10.21)	999 (± 999)		
Global Health Status CFB at Cycle 15, Day 1 n=5,0	10.0 (± 10.87)	999 (± 999)		
Global Health Status CFB at Cycle 17, Day 1 n=4,0	18.8 (± 10.49)	999 (± 999)		
Global Health Status CFB at Cycle 19, Day 1 n=5,0	-1.7 (± 19.00)	999 (± 999)		
Global Health Status CFB at Cycle 21, Day 1 n=4,0	0.0 (± 0.00)	999 (± 999)		
Global Health Status CFB at Cycle 23, Day 1 n=2,0	-8.3 (± 11.79)	999 (± 999)		
Global Health Status CFB at Cycle 25, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Global Health Status CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Global Health Status CFB at Cycle 29, Day 1 n=2,0	-29.2 (± 29.46)	999 (± 999)		
Physical Functioning CFB at Cycle 3, Day 1 n=12,4	11.1 (± 24.01)	-1.7 (± 6.38)		

Physical Functioning CFB at Cycle 5, Day 1 n=8,3	15.0 (± 21.89)	-13.3 (± 23.09)		
Physical Functioning CFB at Cycle 7, Day 1 n=8,1	4.2 (± 26.41)	0.0 (± 999)		
Physical Functioning CFB at Cycle 9, Day 1 n=7,2	7.6 (± 22.25)	3.3 (± 14.14)		
Physical Functioning CFB at Cycle 11, Day 1 n=7,0	-1.9 (± 25.74)	999 (± 999)		
Physical Functioning CFB at Cycle 13, Day 1 n=5,0	5.3 (± 25.99)	999 (± 999)		
Physical Functioning CFB at Cycle 15, Day 1 n=5,0	-1.3 (± 15.92)	999 (± 999)		
Physical Functioning CFB at Cycle 17, Day 1 n=4,0	-5.0 (± 13.74)	999 (± 999)		
Physical Functioning CFB at Cycle 19, Day 1 n=5,0	-2.7 (± 32.52)	999 (± 999)		
Physical Functioning CFB at Cycle 21, Day 1 n=4,0	5.0 (± 10.00)	999 (± 999)		
Physical Functioning CFB at Cycle 23, Day 1 n=2,0	0.0 (± 9.43)	999 (± 999)		
Physical Functioning CFB at Cycle 25, Day 1 n=2,0	13.3 (± 9.43)	999 (± 999)		
Physical Functioning CFB at Cycle 27, Day 1 n=2,0	3.3 (± 4.71)	999 (± 999)		
Physical Functioning CFB at Cycle 29, Day 1 n=2,0	0.0 (± 28.28)	999 (± 999)		
Role Functioning CFB at Cycle 3, Day 1 n=12,4	20.8 (± 22.61)	-4.2 (± 20.97)		
Role Functioning CFB at Cycle 5, Day 1 n=8,3	20.8 (± 29.21)	-5.6 (± 25.46)		
Role Functioning CFB at Cycle 7, Day 1 n=8,1	18.8 (± 28.78)	0.0 (± 999)		
Role Functioning CFB at Cycle 9, Day 1 n=7,2	14.3 (± 22.42)	-8.3 (± 11.79)		
Role Functioning CFB at Cycle 11, Day 1 n=7,0	7.1 (± 26.97)	999 (± 999)		
Role Functioning CFB at Cycle 13, Day 1 n=5,0	13.3 (± 21.73)	999 (± 999)		
Role Functioning CFB at Cycle 15, Day 1 n=5,0	26.7 (± 19.00)	999 (± 999)		
Role Functioning CFB at Cycle 17, Day 1 n=4,0	0.0 (± 13.61)	999 (± 999)		
Role Functioning CFB at Cycle 19, Day 1 n=5,0	16.7 (± 50.00)	999 (± 999)		
Role Functioning CFB at Cycle 21, Day 1 n=4,0	8.3 (± 16.67)	999 (± 999)		
Role Functioning CFB at Cycle 23, Day 1 n=2,0	8.3 (± 11.79)	999 (± 999)		
Role Functioning CFB at Cycle 25, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Role Functioning CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Role Functioning CFB at Cycle 29, Day 1 n=2,0	0.0 (± 47.14)	999 (± 999)		
Emotional Functioning CFB at Cycle 3, Day 1 n=12,4	15.3 (± 32.14)	2.1 (± 7.98)		
Emotional Functioning CFB at Cycle 5, Day 1 n=8,3	15.6 (± 31.32)	11.1 (± 17.35)		
Emotional Functioning CFB at Cycle 7, Day 1 n=8,1	12.5 (± 34.21)	-16.7 (± 999)		
Emotional Functioning CFB at Cycle 9, Day 1 n=7,2	8.3 (± 36.00)	-8.3 (± 11.79)		

Emotional Functioning CFB at Cycle 11, Day 1 n=7,0	1.2 (± 23.29)	999 (± 999)		
Emotional Functioning CFB at Cycle 13, Day 1 n=5,0	18.3 (± 25.28)	999 (± 999)		
Emotional Functioning CFB at Cycle 15, Day 1 n=5,0	16.7 (± 19.54)	999 (± 999)		
Emotional Functioning CFB at Cycle 17, Day 1 n=4,0	8.3 (± 11.79)	999 (± 999)		
Emotional Functioning CFB at Cycle 19, Day 1 n=5,0	15.0 (± 21.57)	999 (± 999)		
Emotional Functioning CFB at Cycle 21, Day 1 n=4,0	16.7 (± 15.21)	999 (± 999)		
Emotional Functioning CFB at Cycle 23, Day 1 n=2,0	0.0 (± 11.79)	999 (± 999)		
Emotional Functioning CFB at Cycle 25, Day 1 n=2,0	8.3 (± 47.14)	999 (± 999)		
Emotional Functioning CFB at Cycle 27, Day 1 n=2,0	-8.3 (± 23.57)	999 (± 999)		
Emotional Functioning CFB at Cycle 29, Day 1 n=2,0	8.3 (± 35.36)	999 (± 999)		
Cognitive Functioning CFB at Cycle 3, Day 1 n=12,4	12.5 (± 23.70)	-8.3 (± 9.62)		
Cognitive Functioning CFB at Cycle 5, Day 1 n=8,3	6.3 (± 29.46)	0.0 (± 16.67)		
Cognitive Functioning CFB at Cycle 7, Day 1 n=8,1	6.3 (± 33.26)	16.7 (± 999)		
Cognitive Functioning CFB at Cycle 9, Day 1 n=7,2	7.1 (± 21.21)	8.3 (± 11.79)		
Cognitive Functioning CFB at Cycle 11, Day 1 n=7,0	4.8 (± 23.00)	999 (± 999)		
Cognitive Functioning CFB at Cycle 13, Day 1 n=5,0	20.0 (± 18.26)	999 (± 999)		
Cognitive Functioning CFB at Cycle 15, Day 1 n=5,0	16.7 (± 16.67)	999 (± 999)		
Cognitive Functioning CFB at Cycle 17, Day 1 n=4,0	8.3 (± 21.52)	999 (± 999)		
Cognitive Functioning CFB at Cycle 19, Day 1 n=5,0	16.7 (± 28.87)	999 (± 999)		
Cognitive Functioning CFB at Cycle 21, Day 1 n=4,0	0.0 (± 13.61)	999 (± 999)		
Cognitive Functioning CFB at Cycle 23, Day 1 n=2,0	8.3 (± 35.36)	999 (± 999)		
Cognitive Functioning CFB at Cycle 25, Day 1 n=2,0	0.0 (± 47.14)	999 (± 999)		
Cognitive Functioning CFB at Cycle 27, Day 1 n=2,0	-8.3 (± 35.36)	999 (± 999)		
Cognitive Functioning CFB at Cycle 29, Day 1 n=2,0	41.7 (± 11.79)	999 (± 999)		
Social Functioning CFB at Cycle 3, Day 1 n=12,4	18.1 (± 37.91)	-4.2 (± 25.00)		
Social Functioning CFB at Cycle 5, Day 1 n=8,3	12.5 (± 44.32)	-22.2 (± 19.25)		
Social Functioning CFB at Cycle 7, Day 1 n=8,1	-2.1 (± 37.20)	0.0 (± 999)		
Social Functioning CFB at Cycle 9, Day 1 n=7,2	0.0 (± 33.33)	0.0 (± 47.14)		
Social Functioning CFB at Cycle 11, Day 1 n=7,0	-2.4 (± 35.26)	999 (± 999)		
Social Functioning CFB at Cycle 13, Day 1 n=5,0	23.3 (± 25.28)	999 (± 999)		
Social Functioning CFB at Cycle 15, Day 1 n=5,0	10.0 (± 25.28)	999 (± 999)		

Social Functioning CFB at Cycle 17, Day 1 n=4,0	16.7 (± 23.57)	999 (± 999)		
Social Functioning CFB at Cycle 19, Day 1 n=5,0	-13.3 (± 13.94)	999 (± 999)		
Social Functioning CFB at Cycle 21, Day 1 n=4,0	-16.7 (± 13.61)	999 (± 999)		
Social Functioning CFB at Cycle 23, Day 1 n=2,0	-8.3 (± 11.79)	999 (± 999)		
Social Functioning CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Social Functioning CFB at Cycle 27, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Social Functioning CFB at Cycle 29, Day 1 n=2,0	-8.3 (± 11.79)	999 (± 999)		
Fatigue CFB at Cycle 3, Day 1 n=12,4	-11.1 (± 31.43)	-11.1 (± 9.07)		
Fatigue CFB at Cycle 5, Day 1 n=8,3	-12.5 (± 27.50)	-14.8 (± 23.13)		
Fatigue CFB at Cycle 7, Day 1 n=8,1	-12.5 (± 29.36)	-22.2 (± 999)		
Fatigue CFB at Cycle 9, Day 1 n=7,2	-12.7 (± 25.20)	-11.1 (± 15.71)		
Fatigue CFB at Cycle 11, Day 1 n=7,0	-7.9 (± 27.75)	999 (± 999)		
Fatigue CFB at Cycle 13, Day 1 n=5,0	-13.3 (± 27.67)	999 (± 999)		
Fatigue CFB at Cycle 15, Day 1 n=5,0	-15.6 (± 16.85)	999 (± 999)		
Fatigue CFB at Cycle 17, Day 1 n=4,0	-5.6 (± 14.34)	999 (± 999)		
Fatigue CFB at Cycle 19, Day 1 n=5,0	-4.4 (± 26.76)	999 (± 999)		
Fatigue CFB at Cycle 21, Day 1 n=4,0	-11.1 (± 15.71)	999 (± 999)		
Fatigue CFB at Cycle 23, Day 1 n=2,0	0.0 (± 0.0)	999 (± 999)		
Fatigue CFB at Cycle 25, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Fatigue CFB at Cycle 27, Day 1 n=2,0	5.6 (± 7.86)	999 (± 999)		
Fatigue CFB at Cycle 29, Day 1 n=2,0	11.1 (± 31.43)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 3, Day 1 n=12,4	-1.4 (± 21.86)	0.0 (± 0.00)		
Nausea and Vomiting CFB at Cycle 5, Day 1 n=8,3	-6.3 (± 26.63)	11.1 (± 9.62)		
Nausea and Vomiting CFB at Cycle 7, Day 1 n=8,1	20.8 (± 39.59)	0.0 (± 999)		
Nausea and Vomiting CFB at Cycle 9, Day 1 n=7,2	0.0 (± 23.57)	0.0 (± 0.00)		
Nausea and Vomiting CFB at Cycle 11, Day 1 n=7,0	4.8 (± 28.41)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 13, Day 1 n=5,0	-3.3 (± 7.45)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 15, Day 1 n=5,0	0.0 (± 16.67)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 17, Day 1 n=4,0	8.3 (± 31.91)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 19, Day 1 n=5,0	20.0 (± 49.16)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 21, Day 1 n=4,0	20.8 (± 34.36)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 23, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 25, Day 1 n=2,0	8.3 (± 35.36)	999 (± 999)		

Nausea and Vomiting CFB at Cycle 27, Day 1 n=2,0	16.7 (± 47.14)	999 (± 999)		
Nausea and Vomiting CFB at Cycle 29, Day 1 n=2,0	8.3 (± 35.36)	999 (± 999)		
Pain CFB at Cycle 3, Day 1 n=12,4	-4.2 (± 41.51)	-25.0 (± 16.67)		
Pain CFB at Cycle 5, Day 1 n=8,3	-2.1 (± 31.42)	5.6 (± 38.49)		
Pain CFB at Cycle 7, Day 1 n=8,1	-4.2 (± 42.49)	-16.7 (± 999)		
Pain CFB at Cycle 9, Day 1 n=7,2	-4.8 (± 29.99)	0.0 (± 0.00)		
Pain CFB at Cycle 11, Day 1 n=7,0	4.8 (± 50.66)	999 (± 999)		
Pain CFB at Cycle 13, Day 1 n=5,0	0.0 (± 54.01)	999 (± 999)		
Pain CFB at Cycle 15, Day 1 n=5,0	-6.7 (± 40.14)	999 (± 999)		
Pain CFB at Cycle 17, Day 1 n=4,0	12.5 (± 77.43)	999 (± 999)		
Pain CFB at Cycle 19, Day 1 n=5,0	6.7 (± 63.03)	999 (± 999)		
Pain CFB at Cycle 21, Day 1 n=4,0	4.2 (± 43.83)	999 (± 999)		
Pain CFB at Cycle 23, Day 1 n=2,0	25.0 (± 35.36)	999 (± 999)		
Pain CFB at Cycle 25, Day 1 n=2,0	16.7 (± 70.71)	999 (± 999)		
Pain CFB at Cycle 27, Day 1 n=2,0	33.3 (± 47.14)	999 (± 999)		
Pain CFB at Cycle 29, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Dyspnea CFB at Cycle 3, Day 1 n=12,4	-13.9 (± 33.21)	0.0 (± 0.00)		
Dyspnea CFB at Cycle 5, Day 1 n=8,3	-12.5 (± 30.54)	11.1 (± 19.25)		
Dyspnea CFB at Cycle 7, Day 1 n=8,1	-4.2 (± 27.82)	-33.3 (± 999)		
Dyspnea CFB at Cycle 9, Day 1 n=7,2	-4.8 (± 23.00)	16.7 (± 23.57)		
Dyspnea CFB at Cycle 11, Day 1 n=7,0	14.3 (± 37.80)	999 (± 999)		
Dyspnea CFB at Cycle 13, Day 1 n=5,0	6.7 (± 27.89)	999 (± 999)		
Dyspnea CFB at Cycle 15, Day 1 n=5,0	20.0 (± 29.81)	999 (± 999)		
Dyspnea CFB at Cycle 17, Day 1 n=4,0	8.3 (± 16.67)	999 (± 999)		
Dyspnea CFB at Cycle 19, Day 1 n=5,0	13.3 (± 29.81)	999 (± 999)		
Dyspnea CFB at Cycle 21, Day 1 n=	16.7 (± 43.03)	999 (± 999)		
Dyspnea CFB at Cycle 23, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Dyspnea CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Dyspnea CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Dyspnea CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Insomnia CFB at Cycle 3, Day 1 n=12,4	-13.9 (± 26.43)	8.3 (± 31.91)		
Insomnia CFB at Cycle 5, Day 1 n=8,3	0.0 (± 25.20)	-22.2 (± 19.25)		
Insomnia CFB at Cycle 7, Day 1 n=8,1	-8.3 (± 34.50)	-33.3 (± 999)		
Insomnia CFB at Cycle 9, Day 1 n=7,2	-4.8 (± 35.63)	0.0 (± 0.00)		
Insomnia CFB at Cycle 11, Day 1 n=7,0	0.0 (± 38.49)	999 (± 999)		
Insomnia CFB at Cycle 13, Day 1 n=5,0	0.0 (± 33.33)	999 (± 999)		
Insomnia CFB at Cycle 15, Day 1 n=5,0	-13.3 (± 38.01)	999 (± 999)		
Insomnia CFB at Cycle 17, Day 1 n=4,0	16.7 (± 43.03)	999 (± 999)		
Insomnia CFB at Cycle 19, Day 1 n=5,0	-6.7 (± 49.44)	999 (± 999)		
Insomnia CFB at Cycle 21, Day 1 n=4,0	0.0 (± 72.01)	999 (± 999)		
Insomnia CFB at Cycle 23, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Insomnia CFB at Cycle 25, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Insomnia CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Insomnia CFB at Cycle 29, Day 1 n=2,0	16.7 (± 70.71)	999 (± 999)		

Appetite Loss CFB at Cycle 3, Day 1 n=12,4	-16.7 (± 38.92)	-8.3 (± 16.67)		
Appetite Loss CFB at Cycle 5, Day 1 n=8,3	4.2 (± 41.55)	-11.1 (± 19.25)		
Appetite Loss CFB at Cycle 7, Day 1 n=8,1	-12.5 (± 24.80)	0.0 (± 999)		
Appetite Loss CFB at Cycle 9, Day 1 n=7,2	-19.0 (± 32.53)	0.0 (± 47.14)		
Appetite Loss CFB at Cycle 11, Day 1 n=7,0	-14.3 (± 42.41)	999 (± 999)		
Appetite Loss CFB at Cycle 13, Day 1 n=5,0	-40.0 (± 36.51)	999 (± 999)		
Appetite Loss CFB at Cycle 15, Day 1 n=5,0	-33.3 (± 47.14)	999 (± 999)		
Appetite Loss CFB at Cycle 17, Day 1 n=4,0	-33.3 (± 47.14)	999 (± 999)		
Appetite Loss CFB at Cycle 19, Day 1 n=5,0	-13.3 (± 73.03)	999 (± 999)		
Appetite Loss CFB at Cycle 21, Day 1 n=4,0	-33.3 (± 47.14)	999 (± 999)		
Appetite Loss CFB at Cycle 23, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Appetite Loss CFB at Cycle 25, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Appetite Loss CFB at Cycle 27, Day 1 n=2,0	-33.3 (± 0.00)	999 (± 999)		
Appetite Loss CFB at Cycle 29, Day 1 n=2,0	-33.3 (± 0.00)	999 (± 999)		
Constipation CFB at Cycle 3, Day 1 n=12,4	2.8 (± 38.82)	-16.7 (± 19.25)		
Constipation CFB at Cycle 5, Day 1 n=8,3	-12.5 (± 35.36)	0.0 (± 33.33)		
Constipation CFB at Cycle 7, Day 1 n=8,1	-4.2 (± 54.74)	-33.3 (± 999)		
Constipation CFB at Cycle 9, Day 1 n=7,2	14.3 (± 26.23)	-33.3 (± 0.00)		
Constipation CFB at Cycle 11, Day 1 n=7,0	-4.8 (± 44.84)	999 (± 999)		
Constipation CFB at Cycle 13, Day 1 n=5,0	-20.0 (± 44.72)	999 (± 999)		
Constipation CFB at Cycle 15, Day 1 n=5,0	-6.7 (± 54.77)	999 (± 999)		
Constipation CFB at Cycle 17, Day 1 n=4,0	-16.7 (± 57.74)	999 (± 999)		
Constipation CFB at Cycle 19, Day 1 n=5,0	-26.7 (± 43.46)	999 (± 999)		
Constipation CFB at Cycle 21, Day 1 n=4,0	-16.7 (± 57.74)	999 (± 999)		
Constipation CFB at Cycle 23, Day 1 n=2,0	33.3 (± 0.00)	999 (± 999)		
Constipation CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Constipation CFB at Cycle 27, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Constipation CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Diarrhea CFB at Cycle 3, Day 1 n=12,4	0.0 (± 24.62)	0.0 (± 0.00)		
Diarrhea CFB at Cycle 5, Day 1 n=8,3	-4.2 (± 11.79)	-22.2 (± 38.49)		
Diarrhea CFB at Cycle 7, Day 1 n=8,1	0.0 (± 17.82)	0.0 (± 999)		
Diarrhea CFB at Cycle 9, Day 1 n=7,2	14.3 (± 17.82)	0.0 (± 0.00)		

Diarrhea CFB at Cycle 11, Day 1 n=7,0	4.8 (± 12.60)	999 (± 999)		
Diarrhea CFB at Cycle 13, Day 1 n=5,0	0.0 (± 0.00)	999 (± 999)		
Diarrhea CFB at Cycle 15, Day 1 n=5,0	6.7 (± 14.91)	999 (± 999)		
Diarrhea CFB at Cycle 17, Day 1 n=4,0	16.7 (± 33.33)	999 (± 999)		
Diarrhea CFB at Cycle 19, Day 1 n=5,0	13.3 (± 29.81)	999 (± 999)		
Diarrhea CFB at Cycle 21, Day 1 n=4,0	8.3 (± 16.67)	999 (± 999)		
Diarrhea CFB at Cycle 23, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Diarrhea CFB at Cycle 25, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Diarrhea CFB at Cycle 27, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Diarrhea CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Financial Difficulties CFB at C3, Day 1 n=12,4	-2.8 (± 26.43)	0.0 (± 0.00)		
Finance Difficulties CFB at Cycle 5, Day 1 n=8,3	-8.3 (± 29.55)	-11.1 (± 19.25)		
Finance Difficulties CFB at Cycle 7, Day 1 n=8,1	-4.2 (± 21.36)	0.0 (± 999)		
Finance Difficulties CFB at Cycle 9, Day 1 n=7,2	0.0 (± 33.33)	-33.3 (± 47.14)		
Finance Difficulties CFB at Cycle 11, Day 1 n=7,0	0.0 (± 19.25)	999 (± 999)		
Finance Difficulties CFB at Cycle 13, Day 1 n=5,0	0.0 (± 23.57)	999 (± 999)		
Finance Difficulties CFB at Cycle 15, Day 1 n=5,0	13.3 (± 18.26)	999 (± 999)		
Finance Difficulties CFB at Cycle 17, Day 1 n=4,0	-8.3 (± 31.91)	999 (± 999)		
Finance Difficulties CFB at Cycle 19, Day 1 n=5,0	13.3 (± 29.81)	999 (± 999)		
Finance Difficulties CFB at Cycle 21, Day 1 n=4,0	25.0 (± 16.67)	999 (± 999)		
Finance Difficulties CFB at Cycle 23, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Finance Difficulties CFB at Cycle 25, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Finance Difficulties CFB at Cycle 27, Day 1 n=2,0	33.3 (± 0.00)	999 (± 999)		
Finance Difficulties CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Score as per European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Lung Cancer Module (QLQ-LC13)

End point title	Change from Baseline in Score as per European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Lung Cancer Module (QLQ-LC13)

End point description:

EORTC QLQ-LC13 is a 13-item lung cancer specific questionnaire. The assessments here included coughing, hemoptysis, dyspnea, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, and pain in other parts and were based on their presence over the previous week. All but the pain domain were scored on a 4 point Likert scale ranging from “not at all” to “very much.” Pain was scored based on its presence, yes or no. Scores were averaged and transformed to 0 to 100. A higher score indicated a higher presence of symptoms. CFB = change from baseline.

End point type	Secondary

End point timeframe:

Baseline, Cycle (C) 3, Day (D) 1 and then every 6 weeks up to approximately 21 months, end of treatment, and 6, 12, and 18 weeks post treatment. Each cycle duration was 21 days.

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: score on a scale				
arithmetic mean (standard deviation)				
Coughing CFB at Cycle 3, Day 1 n=12,4	-19.4 (± 26.43)	16.7 (± 19.25)		
Coughing CFB at Cycle 5, Day 1 n=8,3	-8.3 (± 23.57)	11.1 (± 19.25)		
Coughing CFB at Cycle 7, Day 1 n=8,1	-20.8 (± 24.80)	0.0 (± 999)		
Coughing CFB at Cycle 9, Day 1 n=7,2	-23.8 (± 25.20)	0.0 (± 0.00)		
Coughing CFB at Cycle 11, Day 1 n=7,0	-9.5 (± 37.09)	999 (± 999)		
Coughing CFB at Cycle 13, Day 1 n=5,0	-20.0 (± 29.81)	999 (± 999)		
Coughing CFB at Cycle 15, Day 1 n=5,0	-6.7 (± 36.51)	999 (± 999)		
Coughing CFB at Cycle 17, Day 1 n=4,0	0.0 (± 0.00)	999 (± 999)		
Coughing CFB at Cycle 19, Day 1 n=5,0	-6.7 (± 14.91)	999 (± 999)		
Coughing CFB at Cycle 21, Day 1 n=4,0	-8.3 (± 41.94)	999 (± 999)		
Coughing CFB at Cycle 23, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Coughing CFB at Cycle 25, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Coughing CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Coughing CFB at Cycle 29, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Hemoptysis CFB at Cycle 3, Day 1 n=12,4	0.0 (± 0.00)	8.3 (± 16.67)		
Hemoptysis CFB at Cycle 5, Day 1 n=8,3	0.0 (± 0.00)	0.0 (± 0.00)		
Hemoptysis CFB at Cycle 7, Day 1 n=8,1	4.2 (± 11.79)	0.0 (± 999)		
Hemoptysis CFB at Cycle 9, Day 1 n=7,2	0.0 (± 0.00)	0.0 (± 0.00)		
Hemoptysis CFB at Cycle 11, Day 1 n=7,0	0.0 (± 0.00)	999 (± 999)		
Hemoptysis CFB at Cycle 13, Day 1 n=5,0	0.0 (± 0.00)	999 (± 999)		
Hemoptysis CFB at Cycle 15, Day 1 n=5,0	0.0 (± 0.00)	999 (± 999)		
Hemoptysis CFB at Cycle 17, Day 1 n=4,0	0.0 (± 0.00)	999 (± 999)		
Hemoptysis CFB at Cycle 19, Day 1 n=5,0	13.3 (± 29.81)	999 (± 999)		
Hemoptysis CFB at Cycle 21, Day 1 n=4,0	0.0 (± 0.00)	999 (± 999)		
Hemoptysis CFB at Cycle 23, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Hemoptysis CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Hemoptysis CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		

Hemoptysis CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Dyspnea CFB at Cycle 3, Day 1 n=12,4	-20.4 (± 21.10)	0.0 (± 9.07)		
Dyspnea CFB at Cycle 5, Day 1 n=8,3	-18.1 (± 17.76)	14.8 (± 16.97)		
Dyspnea CFB at Cycle 7, Day 1 n=8,1	-8.3 (± 29.55)	11.1 (± 999)		
Dyspnea CFB at Cycle 9, Day 1 n=7,2	-14.3 (± 33.16)	16.7 (± 23.57)		
Dyspnea CFB at Cycle 11, Day 1 n=7,0	-4.8 (± 32.62)	999 (± 999)		
Dyspnea CFB at Cycle 13, Day 1 n=5,0	-13.3 (± 31.82)	999 (± 999)		
Dyspnea CFB at Cycle 15, Day 1 n=5,0	-11.1 (± 27.22)	999 (± 999)		
Dyspnea CFB at Cycle 17, Day 1 n=4,0	0.0 (± 9.07)	999 (± 999)		
Dyspnea CFB at Cycle 19, Day 1 n=5,0	6.7 (± 30.02)	999 (± 999)		
Dyspnea CFB at Cycle 21, Day 1 n=4,0	-2.8 (± 36.71)	999 (± 999)		
Dyspnea CFB at Cycle 23, Day 1 n=2,0	-5.6 (± 7.86)	999 (± 999)		
Dyspnea CFB at Cycle 25, Day 1 n=2,0	-5.6 (± 7.86)	999 (± 999)		
Dyspnea CFB at Cycle 27, Day 1 n=2,0	-5.6 (± 7.86)	999 (± 999)		
Dyspnea CFB at Cycle 29, Day 1 n=2,0	0.0 (± 15.71)	999 (± 999)		
Sore Mouth CFB at Cycle 3, Day 1 n=12,4	-8.3 (± 25.13)	0.0 (± 0.00)		
Sore Mouth CFB at Cycle 5, Day 1 n=8,3	-4.2 (± 11.79)	0.0 (± 0.00)		
Sore Mouth CFB at Cycle 7, Day 1 n=8,1	-4.2 (± 27.82)	0.0 (± 999)		
Sore Mouth CFB at Cycle 9, Day 1 n=7,2	9.5 (± 16.27)	16.7 (± 23.57)		
Sore Mouth CFB at Cycle 11, Day 1 n=7,0	9.5 (± 16.27)	999 (± 999)		
Sore Mouth CFB at Cycle 13, Day 1 n=5,0	13.3 (± 18.26)	999 (± 999)		
Sore Mouth CFB at Cycle 15, Day 1 n=5,0	13.3 (± 29.81)	999 (± 999)		
Sore Mouth CFB at Cycle 17, Day 1 n=4,0	16.7 (± 33.33)	999 (± 999)		
Sore Mouth CFB at Cycle 19, Day 1 n=5,0	33.3 (± 33.33)	999 (± 999)		
Sore Mouth CFB at Cycle 21, Day 1 n=4,0	8.3 (± 16.67)	999 (± 999)		
Sore Mouth CFB at Cycle 23, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Sore Mouth CFB at Cycle 25, Day 1 n=2,0	33.3 (± 47.14)	999 (± 999)		
Sore Mouth CFB at Cycle 27, Day 1 n=2,0	33.3 (± 47.14)	999 (± 999)		
Sore Mouth CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Dysphagia CFB at Cycle 3, Day 1 n=12,4	0.0 (± 14.21)	0.0 (± 0.00)		
Dysphagia CFB at Cycle 5, Day 1 n=8,3	8.3 (± 23.57)	0.0 (± 0.00)		
Dysphagia CFB at Cycle 7, Day 1 n=8,1	12.5 (± 24.80)	0.0 (± 999)		
Dysphagia CFB at Cycle 9, Day 1 n=7,2	4.8 (± 12.60)	0.0 (± 0.00)		
Dysphagia CFB at Cycle 11, Day 1 n=7,0	9.5 (± 16.27)	999 (± 999)		
Dysphagia CFB at Cycle 13, Day 1 n=5,0	6.7 (± 14.91)	999 (± 999)		
Dysphagia CFB at Cycle 15, Day 1 n=5,0	13.3 (± 18.26)	999 (± 999)		
Dysphagia CFB at Cycle 17, Day 1 n=4,0	25.0 (± 31.91)	999 (± 999)		

Dysphagia CFB at Cycle 19, Day 1 n=5,0	20.0 (± 18.26)	999 (± 999)		
Dysphagia CFB at Cycle 21, Day 1 n=4,0	25.0 (± 31.91)	999 (± 999)		
Dysphagia CFB at Cycle 23, Day 1 n=2,0	33.3 (± 47.14)	999 (± 999)		
Dysphagia CFB at Cycle 25, Day 1 n=2,0	33.3 (± 47.14)	999 (± 999)		
Dysphagia CFB at Cycle 27, Day 1 n=2,0	33.3 (± 47.14)	999 (± 999)		
Dysphagia CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 3, Day 1 n=12,4	13.9 (± 26.43)	8.3 (± 31.91)		
Peripheral Neuropathy CFB at Cycle 5, Day 1 n=8,3	-4.2 (± 11.79)	11.1 (± 38.49)		
Peripheral Neuropathy CFB at Cycle 7, Day 1 n=8,1	20.8 (± 17.25)	-33.3 (± 999)		
Peripheral Neuropathy CFB at Cycle 9, Day 1 n=7,2	28.6 (± 23.00)	-16.7 (± 23.57)		
Peripheral Neuropathy CFB at Cycle 11, Day 1 n=7,0	14.3 (± 17.82)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 13, Day 1 n=5,0	13.3 (± 18.26)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 15, Day 1 n=5,0	6.7 (± 14.91)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 17, Day 1 n=4,0	8.3 (± 16.67)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 19, Day 1 n=5,0	26.7 (± 43.46)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 21, Day 1 n=4,0	25.0 (± 31.91)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 23, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 25, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Peripheral Neuropathy CFB at Cycle 29, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Alopecia CFB at Cycle 3, Day 1 n=12,4	-8.3 (± 20.72)	41.7 (± 41.94)		
Alopecia CFB at Cycle 5, Day 1 n=8,3	-16.7 (± 17.82)	22.2 (± 19.25)		
Alopecia CFB at Cycle 7, Day 1 n=8,1	0.0 (± 25.20)	-33.3 (± 999)		
Alopecia CFB at Cycle 9, Day 1 n=7,2	0.0 (± 19.25)	0.0 (± 47.14)		
Alopecia CFB at Cycle 11, Day 1 n=7,0	9.5 (± 31.71)	999 (± 999)		
Alopecia CFB at Cycle 13, Day 1 n=5,0	13.3 (± 29.81)	999 (± 999)		
Alopecia CFB at Cycle 15, Day 1 n=5,0	0.0 (± 0.00)	999 (± 999)		
Alopecia CFB at Cycle 17, Day 1 n=4,0	0.0 (± 0.00)	999 (± 999)		
Alopecia CFB at Cycle 19, Day 1 n=5,0	20.0 (± 29.81)	999 (± 999)		
Alopecia CFB at Cycle 21, Day 1 n=4,0	8.3 (± 16.67)	999 (± 999)		
Alopecia CFB at Cycle 23, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Alopecia CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Alopecia CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Alopecia CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Pain in Chest CFB at Cycle 3, Day 1 n=12,4	-19.4 (± 22.29)	-8.3 (± 41.94)		
Pain in Chest CFB at Cycle 5, Day 1 n=8,3	-8.3 (± 29.55)	-11.1 (± 50.92)		

Pain in Chest CFB at Cycle 7, Day 1 n=8,1	-25.0 (± 15.43)	-33.3 (± 999)		
Pain in Chest CFB at Cycle 9, Day 1 n=7,2	-23.8 (± 25.20)	0.0 (± 47.14)		
Pain in Chest CFB at Cycle 11, Day 1 n=7,0	-4.8 (± 23.00)	999 (± 999)		
Pain in Chest CFB at Cycle 13, Day 1 n=5,0	-13.3 (± 18.26)	999 (± 999)		
Pain in Chest CFB at Cycle 15, Day 1 n=5,0	-13.3 (± 18.26)	999 (± 999)		
Pain in Chest CFB at Cycle 17, Day 1 n=4,0	0.0 (± 27.22)	999 (± 999)		
Pain in Chest CFB at Cycle 19, Day 1 n=5,0	-20.0 (± 18.26)	999 (± 999)		
Pain in Chest CFB at Cycle 21, Day 1 n=4,0	0.0 (± 38.49)	999 (± 999)		
Pain in Chest CFB at Cycle 23, Day 1 n=2,0	33.3 (± 47.14)	999 (± 999)		
Pain in Chest CFB at Cycle 25, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Pain in Chest CFB at Cycle 27, Day 1 n=2,0	16.7 (± 23.57)	999 (± 999)		
Pain in Chest CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 3, Day 1 n=12,4	-2.8 (± 30.01)	-33.3 (± 38.49)		
Pain in Arm/Shoulder CFB at Cycle 5, Day 1 n=8,3	-8.3 (± 15.43)	-22.2 (± 19.25)		
Pain in Arm/Shoulder CFB at Cycle 7, Day 1 n=8,1	-8.3 (± 34.50)	-33.3 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 9, Day 1 n=7,2	-9.5 (± 37.09)	-16.7 (± 70.71)		
Pain in Arm/Shoulder CFB at Cycle 11, Day 1 n=7,0	-9.5 (± 53.45)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 13, Day 1 n=5,0	-6.7 (± 36.51)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 15, Day 1 n=5,0	-26.7 (± 49.44)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 17, Day 1 n=4,0	-16.7 (± 57.74)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 19, Day 1 n=5,0	-6.7 (± 59.63)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 21, Day 1 n=4,0	-25.0 (± 56.93)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 23, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Pain in Arm/Shoulder CFB at Cycle 29, Day 1 n=2,0	-50.0 (± 70.71)	999 (± 999)		
Pain in Other Parts CFB at Cycle 3, Day 1 n=12,4	-8.3 (± 37.94)	-8.3 (± 16.67)		
Pain in Other Parts CFB at Cycle 5, Day 1 n=8,3	-12.5 (± 17.25)	0.0 (± 0.00)		
Pain in Other Parts CFB at Cycle 7, Day 1 n=8,1	-12.5 (± 35.36)	33.3 (± 999)		
Pain in Other Parts CFB at Cycle 9, Day 1 n=7,2	-9.5 (± 16.27)	16.7 (± 23.57)		
Pain in Other Parts CFB at Cycle 11, Day 1 n=7,0	4.8 (± 35.63)	999 (± 999)		

Pain in Other Parts CFB at Cycle 13, Day 1 n=5,0	-6.7 (± 14.91)	999 (± 999)		
Pain in Other Parts at Cycle 15, Day 1 n=5,0	-13.3 (± 18.26)	999 (± 999)		
Pain in Other Parts CFB at Cycle 17, Day 1 n=4,0	16.7 (± 43.03)	999 (± 999)		
Pain in Other Parts CFB at Cycle 19, Day 1 n=5,0	20.0 (± 44.72)	999 (± 999)		
Pain in Other Parts CFB at Cycle 21, Day 1 n=	8.3 (± 16.67)	999 (± 999)		
Pain in Other Parts CFB at Cycle 23, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Pain in Other Parts CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Pain in Other Parts CFB at Cycle 27, Day 1 n=2,0	-16.7 (± 23.57)	999 (± 999)		
Pain in Other Parts CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Score as per European Quality of Life 5-Dimension 5-Level (EQ-5D-5L) Questionnaire

End point title	Change from Baseline in Score as per European Quality of Life 5-Dimension 5-Level (EQ-5D-5L) Questionnaire

End point description:

EQ-5D-5L is a standardized measure to assess the overall health-related quality of life in patients. The EQ-5D-5L consists of 2 parts– the descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each with 5 levels: from 1 (no problems) to 5 (extreme problems). The EQ VAS is a self-perceived health score assessed using a visual analogue scale that ranges from 0 (the worst imaginable health) to 100 (the best imaginable health), with higher scores indicating higher health utility. CFB = change from baseline.

End point type	Secondary

End point timeframe:

Baseline, Cycle (C) 3, Day (D) 1 and then every 6 weeks up to approximately 21 months, end of treatment, and 6, 12, and 18 weeks post treatment. Each cycle duration was 21 days.

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: score on a scale				
arithmetic mean (standard deviation)				
Anxiety/Depression CFB at Cycle 3, Day 1 n=12,4	-0.6 (± 0.79)	0.0 (± 0.82)		
Anxiety/Depression CFB at Cycle 5, Day 1 n=8,3	-0.3 (± 1.16)	-0.7 (± 1.53)		
Anxiety/Depression CFB at Cycle 7, Day 1 n=8,1	-0.3 (± 1.39)	-1.0 (± 999)		
Anxiety/Depression CFB at Cycle 9, Day 1 n=7,2	0.0 (± 1.41)	0.0 (± 1.41)		

Anxiety/Depression CFB at Cycle 11, Day 1 n=7,0	0.4 (± 0.98)	999 (± 999)		
Anxiety/Depression CFB at Cycle 13, Day 1 n=5,0	-0.4 (± 1.14)	999 (± 999)		
Anxiety/Depression CFB at Cycle 15, Day 1 n=5,0	-0.2 (± 1.10)	999 (± 999)		
Anxiety/Depression CFB at Cycle 17, Day 1 n=4,0	0.5 (± 1.29)	999 (± 999)		
Anxiety/Depression CFB at Cycle 19, Day 1 n=5,0	-0.2 (± 0.84)	999 (± 999)		
Anxiety/Depression CFB at Cycle 21, Day 1 n=4,0	0.5 (± 1.73)	999 (± 999)		
Anxiety/Depression CFB at Cycle 23, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Anxiety/Depression CFB at Cycle 25, Day 1 n=2,0	-0.5 (± 0.71)	999 (± 999)		
Anxiety/Depression CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Anxiety/Depression CFB at Cycle 29, Day 1 n=2,0	0.5 (± 2.12)	999 (± 999)		
EQ VAS Score CFB at Cycle 3, Day 1 n=12,4	11.7 (± 17.99)	10.3 (± 11.32)		
EQ VAS Score CFB at Cycle 5, Day 1 n=8,3	12.6 (± 12.47)	10.3 (± 5.03)		
EQ VAS Score CFB at Cycle 7, Day 1 n=8,1	7.6 (± 15.34)	-6.0 (± 999)		
EQ VAS Score CFB at Cycle 9, Day 1 n=7,2	6.7 (± 18.29)	5.0 (± 8.49)		
EQ VAS Score CFB at Cycle 11, Day 1 n=7,0	-1.4 (± 14.36)	999 (± 999)		
EQ VAS Score CFB at Cycle 13, Day 1 n=5,0	10.8 (± 21.23)	999 (± 999)		
EQ VAS Score CFB at Cycle 15, Day 1 n=5,0	1.6 (± 10.88)	999 (± 999)		
EQ VAS Score CFB at Cycle 17, Day 1 n=4,0	-4.5 (± 13.77)	999 (± 999)		
EQ VAS Score CFB at Cycle 19, Day 1 n=5,0	2.0 (± 12.27)	999 (± 999)		
EQ VAS Score CFB at Cycle 21, Day 1 n=4,0	-5.0 (± 10.80)	999 (± 999)		
EQ VAS Score CFB at Cycle 23, Day 1 n=2,0	-7.5 (± 17.68)	999 (± 999)		
EQ VAS Score CFB at Cycle 25, Day 1 n=2,0	-4.0 (± 26.87)	999 (± 999)		
EQ VAS Score CFB at Cycle 27, Day 1 n=2,0	-17.0 (± 16.97)	999 (± 999)		
EQ VAS Score CFB at Cycle 29, Day 1 n=2,0	-16.5 (± 9.19)	999 (± 999)		
Pain/Discomfort CFB at Cycle 3, Day 1 n=12,4	-0.3 (± 0.89)	0.3 (± 0.96)		
Pain/Discomfort CFB at Cycle 5, Day 1 n=8,3	0.1 (± 0.99)	0.0 (± 1.00)		
Pain/Discomfort CFB at Cycle 7, Day 1 n=8,1	0.4 (± 1.06)	0.0 (± 999)		
Pain/Discomfort CFB at Cycle 9, Day 1 n=7,2	0.0 (± 0.82)	1.0 (± 0.00)		
Pain/Discomfort CFB at Cycle 11, Day 1 n=7,0	0.1 (± 1.57)	999 (± 999)		
Pain/Discomfort CFB at Cycle 13, Day 1 n=5,0	0.6 (± 1.52)	999 (± 999)		
Pain/Discomfort CFB at Cycle 15, Day 1 n=5,0	0.0 (± 1.58)	999 (± 999)		

Pain/Discomfort CFB at Cycle 17, Day 1 n=4,0	0.8 (± 2.22)	999 (± 999)		
Pain/Discomfort CFB at Cycle 19, Day 1 n=5,0	-0.2 (± 1.48)	999 (± 999)		
Pain/Discomfort CFB at Cycle 21, Day 1 n=4,0	0.3 (± 1.71)	999 (± 999)		
Pain/Discomfort CFB at Cycle 23, Day 1 n=2,0	2.0 (± 0.00)	999 (± 999)		
Pain/Discomfort CFB at Cycle 25, Day 1 n=2,0	1.0 (± 1.41)	999 (± 999)		
Pain/Discomfort CFB at Cycle 27, Day 1 n=2,0	1.5 (± 0.71)	999 (± 999)		
Pain/Discomfort CFB at Cycle 29, Day 1 n=2,0	0.5 (± 0.71)	999 (± 999)		
Mobility CFB at Cycle 3, Day 1 n=12,4	-0.3 (± 0.75)	-0.3 (± 0.96)		
Mobility CFB at Cycle 5, Day 1 n=8,3	-0.4 (± 0.92)	0.7 (± 1.53)		
Mobility CFB at Cycle 7, Day 1 n=8,1	-0.1 (± 0.83)	0.0 (± 999)		
Mobility CFB at Cycle 9, Day 1 n=7,2	-0.4 (± 0.98)	1.0 (± 1.41)		
Mobility CFB at Cycle 11, Day 1 n=7,0	-0.1 (± 1.07)	999 (± 999)		
Mobility CFB at Cycle 13, Day 1 n=5,0	-0.2 (± 0.84)	999 (± 999)		
Mobility CFB at Cycle 15, Day 1 n=5,0	0.2 (± 0.45)	999 (± 999)		
Mobility CFB at Cycle 17, Day 1 n=4,0	0.3 (± 0.96)	999 (± 999)		
Mobility CFB at Cycle 19, Day 1 n=5,0	0.0 (± 1.00)	999 (± 999)		
Mobility CFB at Cycle 21, Day 1 n=4,0	-0.3 (± 0.96)	999 (± 999)		
Mobility CFB at Cycle 23, Day 1 n=2,0	0.5 (± 0.71)	999 (± 999)		
Mobility CFB at Cycle 25, Day 1 n=2,0	0.5 (± 0.71)	999 (± 999)		
Mobility CFB at Cycle 27, Day 1 n=2,0	1.0 (± 1.41)	999 (± 999)		
Mobility CFB at Cycle 29, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Self-Care CFB at Cycle 3, Day 1 n=12,4	-0.2 (± 0.72)	0.0 (± 0.00)		
Self-Care CFB at Cycle 5, Day 1 n=8,3	0.5 (± 0.76)	0.0 (± 0.00)		
Self-Care CFB at Cycle 7, Day 1 n=8,1	0.0 (± 1.20)	0.0 (± 999)		
Self-Care CFB at Cycle 9, Day 1 n=7,2	0.1 (± 1.35)	0.0 (± 0.00)		
Self-Care CFB at Cycle 11, Day 1 n=7,0	0.1 (± 1.46)	999 (± 999)		
Self-Care CFB at Cycle 13, Day 1 n=5,0	0.0 (± 1.22)	999 (± 999)		
Self-Care CFB at Cycle 15, Day 1 n=5,0	0.0 (± 1.22)	999 (± 999)		
Self-Care CFB at Cycle 17, Day 1 n=4,0	0.0 (± 1.63)	999 (± 999)		
Self-Care CFB at Cycle 19, Day 1 n=5,0	0.0 (± 1.58)	999 (± 999)		
Self-Care CFB at Cycle 21, Day 1 n=4,0	-0.3 (± 1.71)	999 (± 999)		
Self-Care CFB at Cycle 23, Day 1 n=2,0	1.0 (± 1.41)	999 (± 999)		
Self-Care CFB at Cycle 25, Day 1 n=2,0	1.0 (± 1.41)	999 (± 999)		
Self-Care CFB at Cycle 27, Day 1 n=2,0	1.0 (± 1.41)	999 (± 999)		
Self-Care CFB at Cycle 29, Day 1 n=2,0	-0.5 (± 0.71)	999 (± 999)		
Usual Activities CFB at Cycle 3, Day 1 n=12,4	-0.7 (± 1.23)	1.3 (± 0.50)		
Usual Activities CFB at Cycle 5, Day 1 n=8,3	-0.9 (± 1.55)	0.7 (± 0.58)		
Usual Activities CFB at Cycle 7, Day 1 n=8,1	-0.8 (± 1.28)	0.0 (± 999)		
Usual Activities CFB at Cycle 9, Day 1 n=7,2	-0.7 (± 0.95)	1.5 (± 0.71)		
Usual Activities CFB at Cycle 11, Day 1 n=7,0	-0.7 (± 1.38)	999 (± 999)		
Usual Activities CFB at Cycle 13, Day 1 n=5,0	-0.8 (± 0.84)	999 (± 999)		
Usual Activities CFB at Cycle 15, Day 1 n=5,0	-0.4 (± 0.55)	999 (± 999)		

Usual Activities CFB at Cycle 17, Day 1 n=4,0	-0.3 (± 0.50)	999 (± 999)		
Usual Activities CFB at Cycle 19, Day 1 n=5,0	-0.4 (± 0.55)	999 (± 999)		
Usual Activities CFB at Cycle 21, Day 1 n=4,0	-0.8 (± 0.96)	999 (± 999)		
Usual Activities CFB at Cycle 23, Day 1 n=2,0	0.5 (± 0.71)	999 (± 999)		
Usual Activities CFB at Cycle 25, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Usual Activities CFB at Cycle 27, Day 1 n=2,0	0.0 (± 0.00)	999 (± 999)		
Usual Activities CFB at Cycle 29, Day 1 n=2,0	1.0 (± 1.41)	999 (± 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Symptom Deterioration for Chest Pain, Cough and Dyspnea Assessed Using European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Lung Cancer Module (QLQ-LC13)

End point title	Time to Symptom Deterioration for Chest Pain, Cough and Dyspnea Assessed Using European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Lung Cancer Module (QLQ-LC13)

End point description:

EORTC QLQ-LC13 is a 13-item lung cancer specific questionnaire. The assessments here included chest pain, cough, and dyspnea and were based on their presence over the previous week. All but the pain domain were scored on a 4 point Likert scale ranging from "not at all" to "very much." Pain was scored based on its presence, yes or no. Scores were averaged and transformed to 0 to 100. A higher score indicated a higher presence of symptoms. Time to symptom deterioration for chest pain, cough and dyspnea was assessed. Deterioration was assessed by the investigator.

End point type	Secondary

End point timeframe:

Cycle (C) 1 Day (D) 1, C3 D1 and then every 6 weeks up to approximately 21 months, end of treatment and 6, 12, 18 weeks post treatment. Each cycle duration was 21 days.

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: months				
median (confidence interval 95%)				
Coughing	13.9 (2.76 to 999)	2.9 (1.38 to 999)		
Dyspnea	5.7 (2.76 to 999)	2.9 (1.38 to 999)		
Pain in chest	11.1 (2.76 to 999)	2.9 (1.45 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Deterioration for Global Health Status /QoL Assessed Using European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30

End point title	Time to Deterioration for Global Health Status /QoL Assessed Using European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30

End point description:

EORTC-QLQ-C30 is a 30-item questionnaire developed to assess the quality of life of cancer patients. The questionnaire is composed of both multi-item scales and single-item measures based on the participants experience over the past week. These include five domains (physical, role, emotional, cognitive and social functioning), three symptom scales (fatigue, nausea/vomiting, and pain), six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea and financial impact) and a global health status/HRQoL scale. All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level.
Time to deterioration in QoL from EORTC-QLQ-C30 was assessed. Deterioration was assessed by the investigator.

End point type	Secondary

End point timeframe:

Cycle (C) 1 Day (D) 1, C3 D1 and then every 6 weeks up to approximately 21 months, end of treatment and 6, 12, 18 weeks post treatment. Each cycle duration was 21 days.

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	7		
Units: months				
median (confidence interval 95%)	999 (2.92 to 999)	999 (1.38 to 999)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: All Collected Deaths

End point title	All Collected Deaths

End point description:

On-treatment deaths due to any cause were collected from first dose of study medication to 30 days after the last dose of study treatment. Post-treatment survival follow-up deaths were collected from Day 31 after last dose of study medication to the data cut-off date.

End point type	Post-hoc

End point timeframe:

On-treatment deaths: Up to approximately 117 weeks. Post-treatment survival follow-up deaths: Up to an additional 36 weeks.

End point values	Capmatinib	Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	6		
Units: Participants				
On-treatment deaths	2	0		
Post-treatment deaths	7	5		
All deaths	9	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From day of first dose of study medication to last dose of study medication plus 30 days, up to approximately 117 weeks.	
Adverse event reporting additional description:	
Any sign or symptom that occurred during the conduct of the trial and safety follow-up.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups	
Reporting group title	Capmatinib- randomized treatment
Reporting group description:	
Capmatinib- randomized treatment	
Reporting group title	Capmatinib- extension treatment
Reporting group description:	
Capmatinib- extension treatment	
Reporting group title	Docetaxel- randomized treatment
Reporting group description:	
Docetaxel- randomized treatment	

Serious adverse events	Capmatinib-randomized treatment	Capmatinib-extension treatment	Docetaxel-randomized treatment
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 15 (20.00%)	1 / 5 (20.00%)	2 / 6 (33.33%)
number of deaths (all causes)	2	0	0
number of deaths resulting from adverse events	1	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Infections and infestations			
Sepsis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Capmatinib-randomized treatment	Capmatinib-extension treatment	Docetaxel-randomized treatment
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 15 (93.33%)	4 / 5 (80.00%)	5 / 6 (83.33%)
Vascular disorders			
Lymphoedema			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Deep vein thrombosis			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Embolism			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hypotension			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
Suprapubic pain			

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Peripheral swelling			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	10 / 15 (66.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	12	0	0
Oedema			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Asthenia			
subjects affected / exposed	4 / 15 (26.67%)	2 / 5 (40.00%)	2 / 6 (33.33%)
occurrences (all)	4	3	3
Reproductive system and breast disorders			
Penile dermatitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Perineal rash			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	2	2
Respiratory, thoracic and mediastinal disorders			

Aphonia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	5 / 15 (33.33%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	5	1	1
Dysphonia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Haemoptysis			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Pleural effusion			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Pneumonitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 15 (13.33%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Hiccups			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Anxiety			

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Investigations			
Amylase increased			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	6	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood albumin decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Blood bilirubin increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Blood creatinine increased			
subjects affected / exposed	4 / 15 (26.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	6	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Creatinine renal clearance increased			

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Neutrophil count decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Protein total decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Weight increased			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	3	3
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Fall			

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Palpitations			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pericardial effusion			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Supraventricular extrasystoles			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Dizziness			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Headache			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Hypoaesthesia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Paraesthesia			

subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Somnolence			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 15 (6.67%)	3 / 5 (60.00%)	3 / 6 (50.00%)
occurrences (all)	1	3	3
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Ear pain			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Hypoacusis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Tinnitus			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Eye pruritus			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eyelid oedema			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	1 / 15 (6.67%)	2 / 5 (40.00%)	2 / 6 (33.33%)
occurrences (all)	1	2	2
Vitreous floaters			

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 15 (20.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Gingival bleeding			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Frequent bowel movements			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Faecaloma			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Constipation			
subjects affected / exposed	4 / 15 (26.67%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	4	1	1
Aphthous ulcer			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Abdominal pain upper			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	5 / 15 (33.33%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	8	1	1
Odynophagia			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Stomatitis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Vomiting			
subjects affected / exposed	6 / 15 (40.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	7	0	0
Toothache			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Alopecia			
subjects affected / exposed	1 / 15 (6.67%)	4 / 5 (80.00%)	4 / 6 (66.67%)
occurrences (all)	1	4	4
Dermatosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Night sweats			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Onycholysis			

subjects affected / exposed	0 / 15 (0.00%)	2 / 5 (40.00%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Pain of skin			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Pruritus			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Skin exfoliation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Rash vesicular			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Nocturia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Renal pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Myxoedema			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Back pain			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Bone pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Muscle spasms			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Osteoarthritis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Osteochondrosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	3 / 15 (20.00%)	2 / 5 (40.00%)	2 / 6 (33.33%)
occurrences (all)	5	2	2
Pain in jaw			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Scoliosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Infections and infestations			
Bronchitis			

subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Rhinolaryngitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Respiratory tract infection			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eyelid infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 5 (40.00%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
COVID-19			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 15 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Fluid retention			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Hyperglycaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	3 / 15 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	4 / 15 (26.67%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	5	1	1
Hypoproteinaemia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 December 2020	This amendment included the following changes: Collection of post-progression patient-reported outcomes (PRO) were allowed to capture additional cancer related symptoms; mitigation procedures were added to ensure patient safety and trial integrity in the event of public emergencies such as COVID-19; the primary estimand-related attributes were rephrased to align with capmatinib program protocol standard language; comparison of overall response rate of capmatinib and docetaxel was set as key secondary objective as this would support the assessment of clinical benefit and the interpretation of the primary endpoint results; MET (and ALK, if applicable) testing while participant was still receiving anti-cancer therapy at pre-screening was allowed to facilitate recruitment; Novartis guidelines on Response Assessment in Neuro-oncology (RANO) for brain metastases were added as Appendix 2 to the protocol to support the secondary endpoint assessing intracranial anti-tumor activity of capmatinib in participants with central nervous system (CNS) lesions by blinded independent review committee (BIRC). The definitions of time-to-intracranial response (TTIR) and duration of intracranial response (DOIR) were updated accordingly.
24 February 2022	This amendment included the following changes: MET mutation status - to allow local results also from a validated test according to local regulation and documented as part of the participant's medical record to be used for participant eligibility; serious adverse event (SAE)-reporting - immediate reporting clarified to align with health authority (especially with Federal Institute for Drugs and Medical Devices [BfArM]) requirements.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Notes: