



Clinical trial results:

A Single Center, Randomized, Phase II Study of the combination of Cisplatin and Gemcitabine with or without Tocilizumab, an IL-6R inhibitor, as first-line treatment in patients with locally advanced or metastatic biliary tract cancer.

Summary

EudraCT number	2018-004826-27
Trial protocol	DK
Global end of trial date	11 June 2024

Results information

Result version number	v1 (current)
This version publication date	08 June 2025
First version publication date	08 June 2025

Trial information

Trial identification

Sponsor protocol code	GI1863
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Department of Oncology, Herlev & Gentofte Hospital
Sponsor organisation address	Borgmester Ib Juuls Vej 1, Herlev, Denmark, 2730
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 May 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 June 2024
Global end of trial reached?	Yes
Global end of trial date	11 June 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of gemcitabine/cisplatin plus tocilizumab and gemcitabine/cisplatin, primary:
To compare survival rate at 12 months of cisplatin-gemcitabine + tocilizumab versus cisplatin-gemcitabine in patients with locally advanced or metastatic BTC

Protection of trial subjects:

Patients that signed informed consent and fulfilling eligibility criteria were included. Continued monitoring of standard safety parameters during treatment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 September 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 77
Worldwide total number of subjects	77
EEA total number of subjects	77

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)	35
From 65 to 84 years	42
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was open for recruitment of patients from September 2019 to June 2024. All patients are recruited at a single site: Copenhagen University Hospital - Herlev and Gentofte in Denmark. Trial is prematurely ended due change in treatment guidelines in Denmark for the target population in the trial.

Pre-assignment

Screening details:

Eligible patients were ≥ 18 years with locally advanced or metastatic biliary tract cancer, inoperable due to extension of the disease and no previous cancer treatment. ECOG PS 0-1, with measurable disease and adequate organ and hematologic function.

Period 1

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

Blinding implementation details:

Prior to randomised portion of the trial, a safety cohort of 6 participants recieved experimental treatment (unrandomised). Thereafter 71 participants were randomly assigned to experimental and standard treatment, stratification by Serum CRP level (< 10 mg/L versus ≥ 10 mg/L) and stage of disease (locally advanced vs metastatic).

Arms

Are arms mutually exclusive?	Yes
Arm title	Safety cohort

Arm description:

Gemcitabine and cisplatin in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion

Arm type	Experimental
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg/m² given i.v. on days 1 and 8 of every 21-day cycle.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will recieve a maximum of 8 cycles with Cisplatin. Each cycle consists of 25 mg/m² i.v. on day 1 and day 8 and is repeated every 21 days.

Investigational medicinal product name	Tocilizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

6 mg/kg given i.v. on day 1, repeated every 21 days

Arm title	Arm A - Cis/Gem/Toc
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Arm description:

Cisplatin and gemcitabine in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion

Arm type	Experimental
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg/m² given i.v. on days 1 and 8 of every 21-day cycle.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive a maximum of 8 cycles with Cisplatin. Each cycle consists of 25 mg/m² i.v. on day 1 and day 8 and is repeated every 21 days.

Investigational medicinal product name	Tocilizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

6 mg/kg given i.v. on day 1, repeated every 21 days

Arm title	Arm B - Cis/Gem
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Arm description:

Cisplatin and gemcitabine. Treatment continued until disease progression, unacceptable toxicity, pregnancy, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion

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

Dosage and administration details:

1000 mg/m² given i.v. on days 1 and 8 of every 21-day cycle.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive a maximum of 8 cycles with Cisplatin. Each cycle consists of 25 mg/m² i.v. on day 1 and day 8 and is repeated every 21 days.

Number of subjects in period 1	Safety cohort	Arm A - Cis/Gem/Toc	Arm B - Cis/Gem
Started	6	35	36
Completed	2	23	24
Not completed	4	12	12
Adverse event, serious fatal	-	-	1
Physician decision	-	-	2
Adverse event, non-fatal	1	4	-
Surgery for disease under study	2	2	1
Discontinuation of the trial	-	3	3
Death of participant	-	1	-
Patients wish to discontinue treatment	1	2	5

Baseline characteristics

Reporting groups

Reporting group title	Safety cohort
Reporting group description: Gemcitabine and cisplatin in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion	
Reporting group title	Arm A - Cis/Gem/Toc
Reporting group description: Cisplatin and gemcitabine in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion	
Reporting group title	Arm B - Cis/Gem
Reporting group description: Cisplatin and gemcitabine. Treatment continued until disease progression, unacceptable toxicity, pregnancy, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion	

Reporting group values	Safety cohort	Arm A - Cis/Gem/Toc	Arm B - Cis/Gem
Number of subjects	6	35	36
Age categorical Units: Subjects			
Adults (18-64 years)	3	19	13
From 65-84 years	3	16	23
Age continuous Units: years			
median	64	64	68.5
full range (min-max)	40 to 75	44 to 80	40 to 80
Gender categorical Units: Subjects			
Female	3	23	16
Male	3	12	20
Disease stage Units: Subjects			
Locally advanced disease	1	10	11
Metastatic disease	5	25	25
CRP level Units: Subjects			
CRP < 10mg/l	1	13	15
CRP ≥ 10 mg/l	5	22	21

Reporting group values	Total		
Number of subjects	77		
Age categorical Units: Subjects			
Adults (18-64 years)	35		
From 65-84 years	42		

Age continuous Units: years median full range (min-max)	-		
Gender categorical Units: Subjects			
Female	42		
Male	35		
Disease stage Units: Subjects			
Locally advanced disease	22		
Metastatic disease	55		
CRP level Units: Subjects			
CRP < 10mg/l	29		
CRP ≥ 10 mg/l	48		

End points

End points reporting groups

Reporting group title	Safety cohort
Reporting group description: Gemcitabine and cisplatin in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion	
Reporting group title	Arm A - Cis/Gem/Toc
Reporting group description: Cisplatin and gemcitabine in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion	
Reporting group title	Arm B - Cis/Gem
Reporting group description: Cisplatin and gemcitabine. Treatment continued until disease progression, unacceptable toxicity, pregnancy, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion	

Primary: Overall survival rate at 12 months

End point title	Overall survival rate at 12 months ^[1]
End point description: estimates of OS rate as per Kaplan-Meier. Due to premature discontinuation of trial, patients alive at that time were censored at 11/jul/2024 (=EOT+ 30days Safety FU)	
End point type	Primary
End point timeframe: 12 months from randomisation	

Notes:

[1] - 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: Safety cohort of 6 patients is not included in the efficacy endpoint, which was analysed for patients in the randomised part of the trial only.

End point values	Arm A - Cis/Gem/Toc	Arm B - Cis/Gem		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	36		
Units: percent				
number (confidence interval 95%)	51.6 (32.8 to 67.6)	51.6 (33.6 to 66.9)		

Statistical analyses

Statistical analysis title	Log rank test
Comparison groups	Arm A - Cis/Gem/Toc v Arm B - Cis/Gem

Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority ^[2]
P-value	= 0.632 ^[3]
Method	Logrank

Notes:

[2] - Due to premature discontinuation of trial only 71 out of planned 160 patients recruited/included in the analysis

[3] - Due to premature discontinuation of trial only 71 out of planned 160 patients recruited/included in the analysis

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Time from treatment start to 30 days after last treatment

Adverse event reporting additional description:

All serious AE are reported. Non serious adverse event are reported if events were assessed with causal relationship to study treatment only.

Assessment type	Systematic
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Dictionary used

Dictionary name	NCI-CTCAE
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Dictionary version	5
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Reporting groups

Reporting group title	Safety cohort
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Reporting group description:

Gemcitabine and cisplatin in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion

Reporting group title	Arm A - Cis/Gem/Toc
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Reporting group description:

Cisplatin and gemcitabine in combination with tocilizumab. Treatment continued until disease progression, unacceptable toxicity, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion

Reporting group title	Arm B - Cis/Gem
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Reporting group description:

Cisplatin and gemcitabine. Treatment continued until disease progression, unacceptable toxicity, pregnancy, patient's withdrawal of the informed consent at his/hers own request or investigator's discretion

Serious adverse events	Safety cohort	Arm A - Cis/Gem/Toc	Arm B - Cis/Gem
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	8 / 35 (22.86%)	18 / 36 (50.00%)
number of deaths (all causes)	4	28	26
number of deaths resulting from adverse events	0	0	1
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 35 (2.86%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 35 (5.71%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Stent displacement			
subjects affected / exposed	1 / 6 (16.67%)	0 / 35 (0.00%)	0 / 36 (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
Nervous system disorders			
Stroke			
subjects affected / exposed	0 / 6 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fever			
subjects affected / exposed	1 / 6 (16.67%)	1 / 35 (2.86%)	5 / 36 (13.89%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leg pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shoulder pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	1 / 6 (16.67%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	2 / 6 (33.33%)	1 / 35 (2.86%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perforated ulcer			
subjects affected / exposed	0 / 6 (0.00%)	1 / 35 (2.86%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 35 (2.86%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biloma			
subjects affected / exposed	1 / 6 (16.67%)	0 / 35 (0.00%)	0 / 36 (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
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 35 (2.86%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6 (0.00%) 0 / 0 0 / 0	1 / 35 (2.86%) 0 / 1 0 / 0	2 / 36 (5.56%) 1 / 2 0 / 0
Sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 35 (0.00%) 0 / 0 0 / 0	2 / 36 (5.56%) 0 / 2 0 / 1
Abscess subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 6 (33.33%) 0 / 2 0 / 0	0 / 35 (0.00%) 0 / 0 0 / 0	0 / 36 (0.00%) 0 / 0 0 / 0
Biliary tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: includes terms cholangitis, cholecystitis		
Covid 19 infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 35 (0.00%) 0 / 0 0 / 0	5 / 36 (13.89%) 0 / 18 0 / 0
Infection with unknown focus subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 35 (0.00%) 0 / 0 0 / 0	1 / 36 (2.78%) 0 / 1 0 / 0
Flu subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 35 (0.00%) 0 / 0 0 / 0	1 / 36 (2.78%) 0 / 1 0 / 0
Metabolism and nutrition disorders Diabetes subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6 (0.00%) 0 / 0 0 / 0	0 / 35 (0.00%) 0 / 0 0 / 0	1 / 36 (2.78%) 0 / 1 0 / 0

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

Non-serious adverse events	Safety cohort	Arm A - Cis/Gem/Toc	Arm B - Cis/Gem
Total subjects affected by non-serious adverse events subjects affected / exposed	6 / 6 (100.00%)	35 / 35 (100.00%)	36 / 36 (100.00%)
Investigations			
Neutrophil count decreased subjects affected / exposed	2 / 6 (33.33%)	19 / 35 (54.29%)	12 / 36 (33.33%)
occurrences (all)	2	43	13
Platelet count decreased subjects affected / exposed	1 / 6 (16.67%)	17 / 35 (48.57%)	10 / 36 (27.78%)
occurrences (all)	5	36	12
Vascular disorders			
Thrombophlebits subjects affected / exposed	0 / 6 (0.00%)	3 / 35 (8.57%)	2 / 36 (5.56%)
occurrences (all)	0	3	2
Nervous system disorders			
Peripheral sensory neuropathy subjects affected / exposed	3 / 6 (50.00%)	11 / 35 (31.43%)	12 / 36 (33.33%)
occurrences (all)	4	18	16
Peripheral motor neuropathy subjects affected / exposed	0 / 6 (0.00%)	3 / 35 (8.57%)	2 / 36 (5.56%)
occurrences (all)	0	3	2
Dizziness subjects affected / exposed	3 / 6 (50.00%)	2 / 35 (5.71%)	0 / 36 (0.00%)
occurrences (all)	3	2	0
Blood and lymphatic system disorders			
Anemia subjects affected / exposed	1 / 6 (16.67%)	17 / 35 (48.57%)	22 / 36 (61.11%)
occurrences (all)	1	47	29
General disorders and administration site conditions			

Fatigue subjects affected / exposed occurrences (all)	4 / 6 (66.67%) 8	17 / 35 (48.57%) 27	22 / 36 (61.11%) 31
Edema limbs subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 5	17 / 35 (48.57%) 27	8 / 36 (22.22%) 10
Flu like symptoms subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 2	6 / 35 (17.14%) 7	4 / 36 (11.11%) 5
Fever subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 35 (2.86%) 1	4 / 36 (11.11%) 4
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 4	15 / 35 (42.86%) 20	8 / 36 (22.22%) 9
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	5 / 6 (83.33%) 7	22 / 35 (62.86%) 58	15 / 36 (41.67%) 23
Constipation subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	18 / 35 (51.43%) 26	11 / 36 (30.56%) 11
Mucositis oral subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	11 / 35 (31.43%) 21	7 / 36 (19.44%) 9
Vomiting subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	3 / 35 (8.57%) 3	2 / 36 (5.56%) 2
Diarrhea subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 2	2 / 35 (5.71%) 2	2 / 36 (5.56%) 2
Respiratory, thoracic and mediastinal disorders Dyspnea subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	4 / 35 (11.43%) 5	7 / 36 (19.44%) 9

Epistaxis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 35 (5.71%) 3	2 / 36 (5.56%) 2
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 3	19 / 35 (54.29%) 19	8 / 36 (22.22%) 8
Musculoskeletal and connective tissue disorders Athralgia subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 3 3 / 6 (50.00%) 3	8 / 35 (22.86%) 13 4 / 35 (11.43%) 5	9 / 36 (25.00%) 12 6 / 36 (16.67%) 7
Metabolism and nutrition disorders Anorexia subjects affected / exposed occurrences (all)	5 / 6 (83.33%) 7	10 / 35 (28.57%) 19	6 / 36 (16.67%) 11

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 November 2020	- Exclusion criterium concerning patients needing a negative blood-based tuberculosis (TB) screening test to be included, was updated to "Evidence of active tuberculosis (TB), or suspected latent TB based on medical history (e.g. history of untreated TB or TB exposure) without a subsequent negative TB test" Furthermore, changes have been made concerning estimated recruitment rate, recruitment period and discontinuation of prophylactic G-CSF treatment upon termination of cisplatin treatment.

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.

Premature discontinuation of the trial with only 71 out of planned 160 patients randomised.

Notes: