



Clinical trial results:

Multicenter, randomized, double-blind, placebo-controlled, phase III clinical trial to investigate the efficacy and safety of Dronabinol in the Improvement of ChemOthErapy-induced and tumor-Related symptoms in patients with locally advanced or metastatic pancreatic cancer during first-line chemotherapy (DIsCOvER)

Summary

EudraCT number	2019-000616-28
Trial protocol	AT DE
Global end of trial date	25 September 2024

Results information

Result version number	v2
This version publication date	14 February 2026
First version publication date	23 October 2025
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Number of deaths (all causes) during safety evaluation timeframe is given.

Trial information

Trial identification

Sponsor protocol code	AGMT_DISCOVER
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03984214
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AGMT
Sponsor organisation address	Gentzgasse 60/21, Vienna, Austria, 1180
Public contact	Daniela Wolkersdorfer, AGMT gGmbH, +43 6626404411, d.wolkersdorfer@agmt.at
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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	21 July 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	25 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary endpoint variable is the standardized area under the curve of the EORTC QLQ-C30 symptom summary score over the on-treatment period (scores at visits 1-9).

Protection of trial subjects:

All patients were closely monitored to be able to react immediately to any side effects. Rather mild to moderate side effects were expected from dronabinol therapy and a slow dose increase and a final tapering phase was chosen to allow a safe and manageable treatment. In case of the occurrence of intolerable side effects (e.g. intense fatigue, dizziness, vertigo etc.) the increase of doses could have been interrupted, delayed or the dose may have been decreased in steps until the side effects were on an acceptable level. The patient were advised to continue with the last well tolerated number of droplets of the substance after the recovery.

Supportive therapy for oncological patients was prescribed according to current version of national treatment guidelines.

Dronabinol is not recommended for use in pregnant women and women of child-bearing potential (WOCBP) not using contraception. The inclusion of women of childbearing potential had to follow specific recommendations for contraception and pregnancy testing. Women were advised not to become pregnant during and at least 4 weeks after end of the treatment with dronabinol. Male participants were not required to use birth control during exposure to dronabinol.

Background therapy:

Firstline chemotherapy with FOLFIRINOX or gemcitabine + Abraxane(R) according to investigator's decision.

Evidence for comparator: -

Actual start date of recruitment	16 December 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 95
Country: Number of subjects enrolled	Germany: 14
Worldwide total number of subjects	109
EEA total number of subjects	109

Notes:

Subjects enrolled per age group

In utero	0
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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)	44
From 65 to 84 years	65
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between 16-Dec-2019 and 31-Mar-2024, 109 patients were enrolled in 11 sites in Austria and Germany. 104 patients were exposed to the IMP dronabinol/placebo.

Pre-assignment

Screening details:

Due to slow recruitment initially planned sample size of 140 patients was downsized to 104 patients and the primary endpoint was adopted accordingly. In total 841 patients were screened, while 732 patients did not meet the criteria for inclusion.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Blinding implementation details:

After successful screening the site team registers the patient in the online "Randomizer". The patient was automatically assigned to either Dronabinol or Placebo arm by the allocation of the blinded treatment code. Only the treatment code was visible for site team, monitor or sponsor in the "Randomizer". Each IMP vial (dronabinol or placebo) was labeled with a unique number and could be unblinded with a unblinding list via the sponsor of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Dronabinol

Arm description:

Titration period 4 weeks; maintenance 12 weeks; tapering period 2 weeks

Arm type	Experimental
Investigational medicinal product name	Dronabinol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral drops, solution
Routes of administration	Oral use

Dosage and administration details:

Dronabinol 2.5% oral solution, individual daily dose according to tolerability from 2.5 mg up to 30 mg THC per day

Arm title	Placebo
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Arm description:

Titration period 4 weeks; maintenance 12 weeks; tapering period 2 weeks

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral drops, solution
Routes of administration	Oral use

Dosage and administration details:

Placebo oral solution, individual daily dose according to tolerability from 2.5 mg up to 30 mg THC placebo per day

Number of subjects in period 1	Dronabinol	Placebo
Started	54	55
Study treatment started	51	53
Primary endpoint	32	38
Completed	20	30
Not completed	34	25
Adverse reaction IMP	3	3
Physician decision	2	2
Screening failure	2	2
Patient decision	21	15
Patient not compliant	1	-
Death due to underlying disease	-	1
Worsening general condition	-	1
Serious adverse event	3	-
Death due to panc. cancer prior to treatment start	1	-
Exclusion criterion revealed after randomization	1	1

Baseline characteristics

Reporting groups

Reporting group title	Dronabinol
Reporting group description:	
Titration period 4 weeks; maintenance 12 weeks; tapering period 2 weeks	
Reporting group title	Placebo
Reporting group description:	
Titration period 4 weeks; maintenance 12 weeks; tapering period 2 weeks	

Reporting group values	Dronabinol	Placebo	Total
Number of subjects	54	55	109
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
median	67	68	
full range (min-max)	49 to 83	46 to 82	-
Gender categorical			
Units: Subjects			
Female	29	28	57
Male	25	27	52
Therapy			
Background therapy			
Units: Subjects			
FOLFIRINOX	12	14	26
Gemcitabine+Abraxane	42	41	83
Tumor stage			
Units: Subjects			
Locally advanced	8	6	14
Metastatic	46	49	95

End points

End points reporting groups

Reporting group title	Dronabinol
Reporting group description:	
Titration period 4 weeks; maintenance 12 weeks; tapering period 2 weeks	
Reporting group title	Placebo
Reporting group description:	
Titration period 4 weeks; maintenance 12 weeks; tapering period 2 weeks	
Subject analysis set title	Dronabinol PRO
Subject analysis set type	Per protocol
Subject analysis set description:	
The patient-reported outcome (PRO) population includes all randomized patients who received at least one dose of IMP/placebo and additionally had to complete at least 3 EORTC questionnaires including visit 1. Patients are analyzed according to the treatment group to which they were randomized.	
Subject analysis set title	Placebo PRO
Subject analysis set type	Per protocol
Subject analysis set description:	
The patient-reported outcome (PRO) population includes all randomized patients who received at least one dose of IMP/placebo and additionally had to complete at least 3 EORTC questionnaires including visit 1. Patients are analyzed according to the treatment group to which they were randomized.	

Primary: Standardized area under the curve (sAUC)

End point title	Standardized area under the curve (sAUC)
End point description:	
The primary endpoint is the standardized area under the curve (sAUC) of the EORTC QLQ-C30 Summary Score over the ontreatment period (visit 1-9).	
End point type	Primary
End point timeframe:	
Visit 1 to visit 9 (max. 18 weeks)	

End point values	Dronabinol PRO	Placebo PRO		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	38		
Units: none				
arithmetic mean (standard deviation)				
sAUC(V1-V9)	69.1 (± 15.5)	73.6 (± 13.5)		

Statistical analyses

Statistical analysis title	Primary endpoint
Statistical analysis description:	
Linear regression (least square mean difference)	
Comparison groups	Dronabinol PRO v Placebo PRO

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1963
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.4
upper limit	2.4
Variability estimate	Standard error of the mean
Dispersion value	3.465

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All patients having received at least one dose of the study medication were followed for adverse events for at least 28 days after discontinuing study treatment or completion of study treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Placebo exposed
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Reporting group description:

Safety analysis set - the safety analysis population will be used for all safety analyses and is defined to include all randomized patients with at least one intake/administration of study treatment.

Reporting group title	Dronabinol exposed
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Reporting group description:

Safety analysis set - the safety analysis population is used for all safety analyses and is defined to include all randomized patients with at least one intake/administration of study treatment.

Serious adverse events	Placebo exposed	Dronabinol exposed	
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 53 (47.17%)	30 / 51 (58.82%)	
number of deaths (all causes)	6	8	
number of deaths resulting from adverse events	0	4	
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			

subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malnutrition			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	5 / 53 (9.43%)	4 / 51 (7.84%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Drug eruption			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumothorax			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood glucose decreased			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	3 / 53 (5.66%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrong product administered			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			

subjects affected / exposed	0 / 53 (0.00%)	3 / 51 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Dementia Alzheimer's type			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	2 / 53 (3.77%)	3 / 51 (5.88%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 53 (1.89%)	3 / 51 (5.88%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flatulence			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	1 / 53 (1.89%)	3 / 51 (5.88%)	
occurrences causally related to treatment / all	0 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			

subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chromoblastomycosis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infection			
subjects affected / exposed	5 / 53 (9.43%)	3 / 51 (5.88%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis bacterial			

subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 53 (1.89%)	4 / 51 (7.84%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			

subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3.5 %

Non-serious adverse events	Placebo exposed	Dronabinol exposed	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 53 (94.34%)	49 / 51 (96.08%)	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 53 (1.89%)	3 / 51 (5.88%)	
occurrences (all)	1	3	
Hypotension			
subjects affected / exposed	4 / 53 (7.55%)	4 / 51 (7.84%)	
occurrences (all)	4	5	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 53 (3.77%)	3 / 51 (5.88%)	
occurrences (all)	2	3	
Chills			
subjects affected / exposed	4 / 53 (7.55%)	0 / 51 (0.00%)	
occurrences (all)	4	0	
Fatigue			
subjects affected / exposed	22 / 53 (41.51%)	26 / 51 (50.98%)	
occurrences (all)	29	45	
General physical health deterioration			
subjects affected / exposed	3 / 53 (5.66%)	2 / 51 (3.92%)	
occurrences (all)	4	2	
Mucosal inflammation			

subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 4	3 / 51 (5.88%) 3	
Oedema subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	2 / 51 (3.92%) 2	
Oedema peripheral subjects affected / exposed occurrences (all)	21 / 53 (39.62%) 25	4 / 51 (7.84%) 4	
Pyrexia subjects affected / exposed occurrences (all)	7 / 53 (13.21%) 11	12 / 51 (23.53%) 13	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	4 / 53 (7.55%) 5	6 / 51 (11.76%) 6	
Dyspnoea subjects affected / exposed occurrences (all)	5 / 53 (9.43%) 5	7 / 51 (13.73%) 7	
Epistaxis subjects affected / exposed occurrences (all)	5 / 53 (9.43%) 6	3 / 51 (5.88%) 3	
Psychiatric disorders Aversion subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	2 / 51 (3.92%) 2	
Depression subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 3	1 / 51 (1.96%) 1	
Insomnia subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 4	2 / 51 (3.92%) 2	
Sleep disorder subjects affected / exposed occurrences (all)	4 / 53 (7.55%) 4	2 / 51 (3.92%) 2	
Investigations			

Blood glucose abnormal subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	2 / 51 (3.92%) 2	
Body temperature increased subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	2 / 51 (3.92%) 2	
C-reactive protein increased subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 4	5 / 51 (9.80%) 6	
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 3	0 / 51 (0.00%) 0	
Weight decreased subjects affected / exposed occurrences (all)	8 / 53 (15.09%) 9	4 / 51 (7.84%) 5	
White blood cell count decreased subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 3	1 / 51 (1.96%) 2	
Blood glucose decreased subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	1 / 51 (1.96%) 1	
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	4 / 53 (7.55%) 5	4 / 51 (7.84%) 8	
Dysgeusia subjects affected / exposed occurrences (all)	4 / 53 (7.55%) 4	3 / 51 (5.88%) 3	
Headache subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 3	1 / 51 (1.96%) 1	
Neuropathy peripheral subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 5	0 / 51 (0.00%) 0	
Paraesthesia			

subjects affected / exposed	7 / 53 (13.21%)	2 / 51 (3.92%)	
occurrences (all)	7	4	
Polyneuropathy			
subjects affected / exposed	20 / 53 (37.74%)	19 / 51 (37.25%)	
occurrences (all)	25	25	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	14 / 53 (26.42%)	5 / 51 (9.80%)	
occurrences (all)	20	7	
Neutropenia			
subjects affected / exposed	9 / 53 (16.98%)	12 / 51 (23.53%)	
occurrences (all)	10	15	
Thrombocytopenia			
subjects affected / exposed	5 / 53 (9.43%)	12 / 51 (23.53%)	
occurrences (all)	6	15	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	9 / 53 (16.98%)	9 / 51 (17.65%)	
occurrences (all)	9	9	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	3 / 53 (5.66%)	0 / 51 (0.00%)	
occurrences (all)	3	0	
Abdominal distension			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	
occurrences (all)	2	2	
Abdominal pain			
subjects affected / exposed	11 / 53 (20.75%)	5 / 51 (9.80%)	
occurrences (all)	12	5	
Abdominal pain lower			
subjects affected / exposed	3 / 53 (5.66%)	0 / 51 (0.00%)	
occurrences (all)	3	0	
Abdominal pain upper			
subjects affected / exposed	3 / 53 (5.66%)	2 / 51 (3.92%)	
occurrences (all)	3	3	
Abnormal faeces			

subjects affected / exposed	3 / 53 (5.66%)	0 / 51 (0.00%)	
occurrences (all)	3	0	
Ascites			
subjects affected / exposed	4 / 53 (7.55%)	4 / 51 (7.84%)	
occurrences (all)	7	5	
Constipation			
subjects affected / exposed	8 / 53 (15.09%)	16 / 51 (31.37%)	
occurrences (all)	10	18	
Diarrhoea			
subjects affected / exposed	25 / 53 (47.17%)	20 / 51 (39.22%)	
occurrences (all)	35	22	
Dyspepsia			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	
occurrences (all)	2	1	
Nausea			
subjects affected / exposed	33 / 53 (62.26%)	23 / 51 (45.10%)	
occurrences (all)	40	31	
Vomiting			
subjects affected / exposed	12 / 53 (22.64%)	6 / 51 (11.76%)	
occurrences (all)	18	9	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	6 / 53 (11.32%)	5 / 51 (9.80%)	
occurrences (all)	6	5	
Dry skin			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	
occurrences (all)	2	1	
Erythema			
subjects affected / exposed	2 / 53 (3.77%)	3 / 51 (5.88%)	
occurrences (all)	2	3	
Hyperhidrosis			
subjects affected / exposed	2 / 53 (3.77%)	3 / 51 (5.88%)	
occurrences (all)	4	3	
Night sweats			
subjects affected / exposed	4 / 53 (7.55%)	2 / 51 (3.92%)	
occurrences (all)	6	2	

Pruritus			
subjects affected / exposed	3 / 53 (5.66%)	0 / 51 (0.00%)	
occurrences (all)	3	0	
Rash			
subjects affected / exposed	4 / 53 (7.55%)	6 / 51 (11.76%)	
occurrences (all)	4	8	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 53 (7.55%)	2 / 51 (3.92%)	
occurrences (all)	4	2	
Back pain			
subjects affected / exposed	2 / 53 (3.77%)	4 / 51 (7.84%)	
occurrences (all)	2	5	
Bone pain			
subjects affected / exposed	1 / 53 (1.89%)	3 / 51 (5.88%)	
occurrences (all)	1	3	
Muscular weakness			
subjects affected / exposed	4 / 53 (7.55%)	3 / 51 (5.88%)	
occurrences (all)	4	3	
Pain in extremity			
subjects affected / exposed	3 / 53 (5.66%)	1 / 51 (1.96%)	
occurrences (all)	4	1	
Spinal pain			
subjects affected / exposed	3 / 53 (5.66%)	1 / 51 (1.96%)	
occurrences (all)	4	1	
Infections and infestations			
COVID-19			
subjects affected / exposed	5 / 53 (9.43%)	2 / 51 (3.92%)	
occurrences (all)	5	2	
Erysipelas			
subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	
occurrences (all)	1	2	
Infection			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	
occurrences (all)	2	5	
Nasopharyngitis			

subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	1 / 51 (1.96%) 1	
Pneumonia subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	1 / 51 (1.96%) 1	
Urinary tract infection subjects affected / exposed occurrences (all)	5 / 53 (9.43%) 6	0 / 51 (0.00%) 0	
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	12 / 53 (22.64%) 17	9 / 51 (17.65%) 10	
Hypokalaemia subjects affected / exposed occurrences (all)	7 / 53 (13.21%) 11	8 / 51 (15.69%) 9	
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	2 / 51 (3.92%) 2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 February 2021	Due to slow recruitment and higher drop-out rate, sample size was downsized. According to guidelines for assessing quality of life in EORTC clinical trials a difference of 10-20% is regarded a moderate change. Thus, it was decided that a sample size of 104 patients instead of 140 patients is large enough to show a difference in the summary score of 20% between the treatment groups with a power of 80%.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported