



Clinical trial results:

A prospective randomized phase II trial of FOLFIRINOX alone versus FOLFIRINOX followed by radiochemotherapy in patients with locally advanced, primarily inoperable pancreatic cancer

Summary

EudraCT number	2012-001850-24
Trial protocol	AT
Global end of trial date	19 November 2024

Results information

Result version number	v1 (current)
This version publication date	25 December 2025
First version publication date	25 December 2025

Trial information

Trial identification

Sponsor protocol code	ABCSG_P02
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ABCSG
Sponsor organisation address	Nussdorfer Platz 8/12, Wien, Austria, 1190
Public contact	Trial Office, ABCSG (Austrian Breast & Colorectal Cancer Study Group), +43 14089230, info@abcsbg.at
Scientific contact	Trial Office, ABCSG (Austrian Breast & Colorectal Cancer Study Group), +43 14089230, info@abcsbg.at

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	14 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 October 2023
Global end of trial reached?	Yes
Global end of trial date	19 November 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that in patients suffering from a primarily inoperable LAPC neoadjuvant chemotherapy followed by concurrent neoadjuvant radiochemotherapy is superior to neoadjuvant chemotherapy alone in terms of R0-resectability

Protection of trial subjects:

A Data Monitoring Committee (DMC) was established to obtain patient safety. The responsibility of the DMC was to evaluate deviations of medical relevance and safety issues. The DMC decided whether or not the patient should continue the study treatment due to safety issues. Important protocol deviations (IPDs) include all deviations endangering the basal medical concept of the study jeopardizing the safety of the patient. Protocol deviations (PDs) include all other protocol deviations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 May 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 83
Worldwide total number of subjects	83
EEA total number of subjects	83

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	51

From 65 to 84 years	32
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Originally, the recruitment phase was planned for 36 months and was prolonged to 54 months in the protocol amendment 4.0. The actual recruitment period lasted 55 months (May 2017 - Dec 2021).

Pre-assignment

Screening details:

Screening assessments to confirm eligibility had to be performed within 28 days prior to randomization unless otherwise indicated.

Pre-assignment period milestones

Number of subjects started	83
Number of subjects completed	83

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Folfinirox alone

Arm description:

6 months of neoadjuvant chemotherapy with Folfinirox (2 phases of three months each)

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

Dosage and administration details:

85 mg/m² as a 2-hours infusion

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

Dosage and administration details:

165 mg/m² as a 90-minutes infusion

Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	CALCIUM FOLINATE, , Folinic acid (Leucovorin)
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

200 mg/m² or 400 mg/m² given as a 2-hours infusion

Investigational medicinal product name	Fluorouracil
Investigational medicinal product code	
Other name	FLUOROURACIL SODIUM
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 2400 mg/m ² as a 46-hours infusion	
Arm title	Folfinirox + radiochemotherapy
Arm description: 3 months of neoadjuvant chemotherapy with Folfinirox plus concurrent neoadjuvant radiochemotherapy (radiotherapy plus concomitant capecitabine) administered on 28 working days during a time period of a minimum of 38 days and a maximum of 47 days (capecitabine intake only on days of radiotherapy)	
Arm type	Experimental
Investigational medicinal product name	Oxaliplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: 85 mg/m ² as a 2-hours infusion	
Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 165 mg/m ² as a 90-minutes infusion	
Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	CALCIUM FOLINATE, FOLINATE, Folinic acid (Leucovorin)
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: 200 mg/m ² or 400 mg/m ² given as a 2-hours infusion	
Investigational medicinal product name	Fluorouracil
Investigational medicinal product code	
Other name	FLUOROURACIL SODIUM
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 2400 mg/m ² as a 46-hours infusion	
Investigational medicinal product name	Capecitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 825 mg/m ² twice daily	

Number of subjects in period 1	Folfinirox alone	Folfinirox + radiochemotherapy
Started	41	42
Completed	5	6
Not completed	36	36
Adverse event, serious fatal	30	30
Consent withdrawn by subject	5	3
Study termination by the sponsor	1	-
Lost to follow-up	-	3

Baseline characteristics

Reporting groups

Reporting group title	Folfinirox alone
Reporting group description: 6 months of neoadjuvant chemotherapy with Folfinirox (2 phases of three months each)	
Reporting group title	Folfinirox + radiochemotherapy
Reporting group description: 3 months of neoadjuvant chemotherapy with Folfinirox plus concurrent neoadjuvant radiochemotherapy (radiotherapy plus concomitant capecitabine) administered on 28 working days during a time period of a minimum of 38 days and a maximum of 47 days (capecitabine intake only on days of radiotherapy)	

Reporting group values	Folfinirox alone	Folfinirox + radiochemotherapy	Total
Number of subjects	41	42	83
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	60.0	62.5	
full range (min-max)	44.0 to 78.0	44.0 to 78.0	-
Gender categorical			
Units: Subjects			
Female	15	17	32
Male	26	25	51
Karnofsky Performance Scale			
Index to classify patients as to their functional impairment: 90%-100%: Fully active; able to carry on all pre-disease performance without restriction 70%-80%: Restricted in physically strenuous activity but ambulatory			
Units: Subjects			
70%-80%	6	8	14
90%-100%	15	11	26
Unknown	20	23	43
Eastern Cooperative Oncology Group (ECOG) performance status			
Scale to measure a cancer patient's level of physical functioning and daily activity Scale 0: Fully active, able to carry out all pre-disease performance without restriction Scale 1: Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work			
Units: Subjects			
Scale 0	30	31	61

Scale 1	10	11	21
Unknown	1	0	1
Electrocardiogram (ECG)			
Units: Subjects			
Abnormal, clinically significant	2	2	4
Abnormal, not clinically significant	14	9	23
Normal	24	25	49
Unknown	1	6	7
Tumor classification			
Units: Subjects			
Irresectable - borderline	14	15	29
Irresectable - locally advanced	27	27	54
Irresectability details			
Units: Subjects			
Arterial (HA, SMA) involvement	6	5	11
Arterial and venous (PV, SMV, HA, SMA) involvement	20	24	44
Cross infiltration of several vital structures	5	4	9
Venous (PV, SMV) involvement	10	9	19
T-stage			
T-stage is primarily determined by tumor size (AJCC/UICC 8th ed.). T4 is defined by the tumor's involvement of other structures. T1: Tumor is 2 cm or less in greatest dimension T2: Tumor is more than 2 cm but not more than 4 cm in greatest dimension T3: Tumor is more than 4 cm in greatest dimension T4: Tumor is unresectable due to invasion of major blood vessels, including the celiac axis and/or superior mesenteric artery			
Units: Subjects			
T1	0	0	0
T2	8	10	18
T3	6	6	12
T4	8	7	15
Unknown	19	19	38
N-stage			
N staging is based on the number of positive lymph nodes (AJCC/UICC 8th ed.) N0: No regional lymph node metastasis N1: Metastasis in one to three regional lymph nodes N2: Metastasis in four or more regional lymph nodes NX: not determinable			
Units: Subjects			
N0	12	8	20
N1	8	10	18
N2	1	2	3
NX	0	3	3
Unknown	20	19	39
M-stage			
M-stage indicates whether the cancer has spread to distant parts of the body (M1) or not (M0)			
Units: Subjects			
M0	40	41	81
M1	1	1	2
Body Mass Index (BMI)			
Units: Subjects			
Underweight	4	1	5
Normal weight	19	20	39

Overweight	11	15	26
Obesity	7	6	13

End points

End points reporting groups

Reporting group title	Folfinirox alone
Reporting group description: 6 months of neoadjuvant chemotherapy with Folfinirox (2 phases of three months each)	
Reporting group title	Folfinirox + radiochemotherapy
Reporting group description: 3 months of neoadjuvant chemotherapy with Folfinirox plus concurrent neoadjuvant radiochemotherapy (radiotherapy plus concomitant capecitabine) administered on 28 working days during a time period of a minimum of 38 days and a maximum of 47 days (capecitabine intake only on days of radiotherapy)	

Primary: R0 resection rate

End point title	R0 resection rate
End point description: R0 resection: (clear resection margin) defined as continuous tumor free rim of tissue of at least 1 mm to the entire circumferential resection margin R0: no tumor cells at margins Non R0: includes R1 patients (microscopic tumor cells at margins; 11), patients who were not evaluated (9) and patients without surgery (41)	
End point type	Primary
End point timeframe: At surgery approx. 4.5 months (Folfinirox alone arm) or 6.4 months (Folfinirox + radiochemotherapy arm) after randomisation	

End point values	Folfinirox alone	Folfinirox + radiochemtherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	42		
Units: Subjects				
R0	9	13		
Non R0	32	29		

Statistical analyses

Statistical analysis title	Chi-square test
Comparison groups	Folfinirox alone v Folfinirox + radiochemotherapy
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.353
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.9
upper limit	27.9

Secondary: Tumor response by modified RECIST

End point title	Tumor response by modified RECIST
End point description:	
Response Criteria in Solid Tumors (RECIST) v1.1 as standard approach to evaluation of study treatments for objective response	
Complete Response (CR): Disappearance of target lesion	
Partial Response (PR): At least 30% decrease of diameter of target lesion, taking as reference the baseline diameter of target lesion	
Progressive Disease (PD): At least a 20% increase in diameter of target lesion. Additionally, the diameter must also demonstrate an absolute increase of at least 5 mm	
Stable Disease (SD): Neither sufficient shrinkage to qualify for PR, nor sufficient increase to qualify for PD (reference: smallest diameter)	
End point type	Secondary
End point timeframe:	
At surgery approx. 4.5 months (Folfinirox alone arm) or 6.4 months (Folfinirox + radiochemotherapy arm) after randomisation	

End point values	Folfinirox alone	Folfinirox + radiochemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	42		
Units: Subjects				
Complete Response (CR)	0	0		
Partial Response (PR)	4	13		
Progressive Disease (PD)	1	3		
Stable Disease (SD)	11	11		
Unknown	25	15		

Statistical analyses

Statistical analysis title	Fishers Exact test
Comparison groups	Folfinirox alone v Folfinirox + radiochemotherapy
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034 ^[1]
Method	Fisher exact

Notes:

[1] - Note that the category "Unknown" was included in the test which accounted for a large portion of the difference. Without including this category, the test is no longer significant, but still the differences in the response rates are remarkably large.

Secondary: Histopathological tumor response

End point title	Histopathological tumor response
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End point description:

Histo-pathological tumor response with respect to proportion of severely degenerative cancer cells
Marked response: No residual tumor or rare, single cancer cells or small groups of cancer cells (glands) with marked cytopathic effect present within a fibrotic stroma

Minimal to moderate response: Residual tumor present; includes small groups of cells/glands without evidence of cytopathic effect, cells/glands outside the main fibrotic mass, and/or >5% of the main fibrotic mass with cancer/gland, with or without cytopathic effect

Poor response: No definite evidence of treatment effect; extensive (> 90%) residual cancer; only minimal cytopathic effect, and baseline fibrosis is present

End point type	Secondary
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End point timeframe:

At surgery approx. 4.5 months (Folfinirox alone arm) or 6.4 months (Folfinirox + radiochemtherapy arm) after randomisation

End point values	Folfinirox alone	Folfinirox + radiochemtherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	42		
Units: Subjects				
Marked response	6	8		
Minimal to moderate response	5	7		
Poor response	4	2		
No assessment done	5	5		
No surgery	21	20		

Statistical analyses

Statistical analysis title	Fishers Exact test
Comparison groups	Folfinirox alone v Folfinirox + radiochemtherapy
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.88
Method	Fisher exact

Secondary: Perioperative complications

End point title	Perioperative complications
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End point description:

Clavien and Dindo classification of surgical complications

Grade I: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions

Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications

Grade IIIa: Intervention not under general anesthesia

Grade IIIb: Intervention under general anesthesia

Grade IVa: Single organ dysfunction (including dialysis)

Grade IVb: Multi organ dysfunction

Grade V: Death of a patient

End point type	Secondary
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End point timeframe:

At surgery approx. 4.5 months (Folfinirox alone arm) or 6.4 months (Folfinirox + radiochemotherapy arm) after randomisation

End point values	Folfinirox alone	Folfinirox + radiochemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20 ^[2]	22 ^[3]		
Units: Subjects				
Grade I	0	3		
Grade II	0	1		
Grade IIIa	2	1		
Grade IIIb	1	1		
Grade IVa	0	0		
Grade IVb	0	2		
Grade V	1	0		
No complications	14	11		
No assessment done	1	3		
Unknown	1	0		

Notes:

[2] - Only patients with surgeries included

[3] - Only patients with surgeries included

Statistical analyses

Statistical analysis title	Fishers Exact test
Comparison groups	Folfinirox alone v Folfinirox + radiochemotherapy
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.287
Method	Fisher exact

Secondary: Progression-free survival (PFS)

End point title	Progression-free survival (PFS)
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End point description:

Progression free survival (PFS) is defined as the time interval during and after treatment until disease progression. For the purpose of this study, PFS was calculated in all participants from the date of randomization until the first clinical/radiological evidence of progression or recurrence of PDAC or death. Progressions after surgeries were not considered as events, because per documentation guideline progressions only had to be documented prior to surgery or in case no surgery was performed.

Participants who were progression free were censored with the last contact date.

End point type	Secondary
End point timeframe:	
Approx. 36 months after the last patient performed the end-of-treatment visit (28-35 days after surgery)	

End point values	Folfirinox alone	Folfirinox + radiochemtherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	42		
Units: months				
median (confidence interval 95%)	10.1 (4.7 to 15.0)	7.2 (5.9 to 10.4)		

Statistical analyses

Statistical analysis title	Log-rank test
Comparison groups	Folfirinox alone v Folfirinox + radiochemtherapy
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7533
Method	Logrank

Secondary: Disease-free survival (DFS)

End point title	Disease-free survival (DFS)
End point description:	
Disease free survival (DFS) is defined as the length of time after surgery for pancreatic ductal adenocarcinoma during which a participant survives with no evidence of the disease. For the purpose of this study, DFS was calculated in participants undergoing R0 pancreatic resection as the time from the date of surgery until the first clinical/radiological evidence of recurrence of PDAC or death (secondary cancers were not included). Participants who were event free were censored with the last contact date. Participants with metastatic disease (M1) at surgery were included with event day = 1. Survival rate estimates at 36 months with 2-sided 95% confidence intervals were calculated using the Kaplan-Meier method.	
End point type	Secondary
End point timeframe:	
Approx. 36 months after the last patient performed the end-of-treatment visit (28-35 days after surgery)	

End point values	Folfinirox alone	Folfinirox + radiochemther apy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	13		
Units: percent				
number (confidence interval 95%)	33.3 (7.8 to 62.3)	23.1 (5.6 to 47.5)		

Statistical analyses

Statistical analysis title	Log-rank test
Comparison groups	Folfinirox alone v Folfinirox + radiochemtherapy
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8299
Method	Logrank

Secondary: Overall survival (OS)

End point title	Overall survival (OS)
End point description:	Overall survival (OS) was calculated in all participants included in the study from the date of randomization until death from any cause. Participants without death date were censored with the end of follow up / last contact date.
End point type	Secondary
End point timeframe:	Approx. 36 months after the last patient performed the end-of-treatment visit (28-35 days after surgery)

End point values	Folfinirox alone	Folfinirox + radiochemther apy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	42		
Units: months				
median (confidence interval 95%)	21.4 (15.8 to 25.4)	19.3 (12.1 to 28.2)		

Statistical analyses

Statistical analysis title	Log-rank test
Comparison groups	Folfinirox alone v Folfinirox + radiochemtherapy

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7659
Method	Logrank

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Start: date of the first dose of the study treatment; End: 28 days after the last dose of the study treatment

Adverse event reporting additional description:

ABCSG P02 Treatment Emergent Adverse Events

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Radiochemotherapy
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Reporting group description: -

Reporting group title	Folfirinox
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Reporting group description: -

Serious adverse events	Radiochemotherapy	Folfirinox	
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 42 (47.62%)	22 / 41 (53.66%)	
number of deaths (all causes)	30	30	
number of deaths resulting from adverse events	1	1	
Vascular disorders			
Subclavian vein thrombosis	Additional description: Subclavian vein thrombosis		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis	Additional description: Jugular vein thrombosis		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis	Additional description: Venous thrombosis		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia	Additional description: Pyrexia		

subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	3 / 42 (7.14%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	2 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue	Additional description: Fatigue		
subjects affected / exposed	2 / 42 (4.76%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation	Additional description: Device dislocation		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Gastroenteritis radiation	Additional description: Gastroenteritis radiation		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion	Additional description: Concussion		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (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			
Febrile neutropenia	Additional description: Febrile neutropenia		

subjects affected / exposed	2 / 42 (4.76%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia	Additional description: Pancytopenia		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	2 / 42 (4.76%)	2 / 41 (4.88%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	2 / 42 (4.76%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer perforation	Additional description: Anastomotic ulcer perforation		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic	Additional description: Ileus paralytic		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	4 / 42 (9.52%)	5 / 41 (12.20%)	
occurrences causally related to treatment / all	5 / 5	5 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		

subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis	Additional description: Haematemesis		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vomiting	Additional description: Vomiting		
subjects affected / exposed	1 / 42 (2.38%)	2 / 41 (4.88%)	
occurrences causally related to treatment / all	2 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea	Additional description: Nausea		
subjects affected / exposed	2 / 42 (4.76%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis	Additional description: Colitis		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure	Additional description: Hepatic failure		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis	Additional description: Portal vein thrombosis		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis	Additional description: Cholestasis		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis	Additional description: Cholangitis		

subjects affected / exposed	2 / 42 (4.76%)	5 / 41 (12.20%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biloma	Additional description: Biloma		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal colic	Additional description: Renal colic		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal vein thrombosis	Additional description: Renal vein thrombosis		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Haematoma muscle	Additional description: Haematoma muscle		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (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			
Staphylococcal infection	Additional description: Staphylococcal infection		
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Sepsis	Additional description: Sepsis		
	subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)
	occurrences causally related to treatment / all	1 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia	Additional description: Pneumonia		
	subjects affected / exposed	2 / 42 (4.76%)	1 / 41 (2.44%)
	occurrences causally related to treatment / all	2 / 2	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis	Additional description: Peritonitis		
	subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)
	occurrences causally related to treatment / all	0 / 0	0 / 2
	deaths causally related to treatment / all	0 / 0	0 / 1
Febrile infection	Additional description: Febrile infection		
	subjects affected / exposed	2 / 42 (4.76%)	1 / 41 (2.44%)
	occurrences causally related to treatment / all	0 / 3	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection	Additional description: Device related infection		
	subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)
	occurrences causally related to treatment / all	0 / 0	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis	Additional description: Clostridium difficile colitis		
	subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)
	occurrences causally related to treatment / all	0 / 0	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
COVID-19	Additional description: COVID-19		
	subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis	Additional description: Bronchitis		
	subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)
	occurrences causally related to treatment / all	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection	Additional description: Viral infection		

subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	2 / 42 (4.76%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Malnutrition	Additional description: Malnutrition		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome	Additional description: Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Radiochemotherapy	Folfirinox	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 42 (97.62%)	41 / 41 (100.00%)	
Vascular disorders			
Hypertension	Additional description: Hypertension		
subjects affected / exposed	9 / 42 (21.43%)	2 / 41 (4.88%)	
occurrences (all)	14	2	
Hypotension	Additional description: Hypotension		
subjects affected / exposed	3 / 42 (7.14%)	0 / 41 (0.00%)	
occurrences (all)	3	0	
General disorders and administration site conditions			
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	4 / 42 (9.52%)	7 / 41 (17.07%)	
occurrences (all)	4	10	
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	4 / 42 (9.52%)	5 / 41 (12.20%)	
occurrences (all)	4	6	
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	1 / 42 (2.38%)	4 / 41 (9.76%)	
occurrences (all)	2	5	
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	2 / 42 (4.76%)	4 / 41 (9.76%)	
occurrences (all)	2	4	
Fatigue	Additional description: Fatigue		
subjects affected / exposed	22 / 42 (52.38%)	17 / 41 (41.46%)	
occurrences (all)	38	27	
Respiratory, thoracic and mediastinal disorders			
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	4 / 42 (9.52%)	1 / 41 (2.44%)	
occurrences (all)	4	1	
Psychiatric disorders			
Anxiety	Additional description: Anxiety		
subjects affected / exposed	0 / 42 (0.00%)	4 / 41 (9.76%)	
occurrences (all)	0	4	
Insomnia	Additional description: Insomnia		

subjects affected / exposed	4 / 42 (9.52%)	1 / 41 (2.44%)	
occurrences (all)	4	1	
Restlessness	Additional description: Restlessness		
subjects affected / exposed	3 / 42 (7.14%)	1 / 41 (2.44%)	
occurrences (all)	3	1	
Sleep disorder	Additional description: Sleep disorder		
subjects affected / exposed	2 / 42 (4.76%)	4 / 41 (9.76%)	
occurrences (all)	2	14	
Investigations			
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	4 / 42 (9.52%)	1 / 41 (2.44%)	
occurrences (all)	5	3	
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	1 / 42 (2.38%)	3 / 41 (7.32%)	
occurrences (all)	1	3	
Nervous system disorders			
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	2 / 42 (4.76%)	7 / 41 (17.07%)	
occurrences (all)	2	7	
Headache	Additional description: Headache		
subjects affected / exposed	3 / 42 (7.14%)	0 / 41 (0.00%)	
occurrences (all)	3	0	
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	9 / 42 (21.43%)	4 / 41 (9.76%)	
occurrences (all)	9	5	
Polyneuropathy	Additional description: Polyneuropathy		
subjects affected / exposed	17 / 42 (40.48%)	26 / 41 (63.41%)	
occurrences (all)	25	38	
Blood and lymphatic system disorders			
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	15 / 42 (35.71%)	16 / 41 (39.02%)	
occurrences (all)	22	20	
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	3 / 42 (7.14%)	2 / 41 (4.88%)	
occurrences (all)	4	4	
Leukopenia	Additional description: Leukopenia		

subjects affected / exposed	8 / 42 (19.05%)	5 / 41 (12.20%)	
occurrences (all)	17	8	
Anaemia	Additional description: Anaemia		
subjects affected / exposed	10 / 42 (23.81%)	9 / 41 (21.95%)	
occurrences (all)	19	14	
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	7 / 42 (16.67%)	9 / 41 (21.95%)	
occurrences (all)	21	16	
Ear and labyrinth disorders			
Vertigo	Additional description: Vertigo		
subjects affected / exposed	6 / 42 (14.29%)	2 / 41 (4.88%)	
occurrences (all)	6	3	
Gastrointestinal disorders			
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	33 / 42 (78.57%)	28 / 41 (68.29%)	
occurrences (all)	62	59	
Constipation	Additional description: Constipation		
subjects affected / exposed	9 / 42 (21.43%)	9 / 41 (21.95%)	
occurrences (all)	15	12	
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	3 / 42 (7.14%)	3 / 41 (7.32%)	
occurrences (all)	3	3	
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	10 / 42 (23.81%)	9 / 41 (21.95%)	
occurrences (all)	10	13	
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	5 / 42 (11.90%)	2 / 41 (4.88%)	
occurrences (all)	7	2	
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	7 / 42 (16.67%)	0 / 41 (0.00%)	
occurrences (all)	7	0	
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	3 / 42 (7.14%)	3 / 41 (7.32%)	
occurrences (all)	4	3	
Vomiting	Additional description: Vomiting		

subjects affected / exposed	14 / 42 (33.33%)	8 / 41 (19.51%)	
occurrences (all)	26	17	
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	3 / 42 (7.14%)	4 / 41 (9.76%)	
occurrences (all)	3	6	
Nausea	Additional description: Nausea		
subjects affected / exposed	32 / 42 (76.19%)	24 / 41 (58.54%)	
occurrences (all)	66	45	
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	3 / 42 (7.14%)	1 / 41 (2.44%)	
occurrences (all)	3	1	
Flatulence	Additional description: Flatulence		
subjects affected / exposed	3 / 42 (7.14%)	3 / 41 (7.32%)	
occurrences (all)	3	3	
Skin and subcutaneous tissue disorders			
Rash	Additional description: Rash		
subjects affected / exposed	3 / 42 (7.14%)	1 / 41 (2.44%)	
occurrences (all)	3	1	
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	1 / 42 (2.38%)	3 / 41 (7.32%)	
occurrences (all)	1	3	
Erythema	Additional description: Erythema		
subjects affected / exposed	3 / 42 (7.14%)	0 / 41 (0.00%)	
occurrences (all)	4	0	
Alopecia	Additional description: Alopecia		
subjects affected / exposed	3 / 42 (7.14%)	3 / 41 (7.32%)	
occurrences (all)	4	3	
Renal and urinary disorders			
Nocturia	Additional description: Nocturia		
subjects affected / exposed	3 / 42 (7.14%)	1 / 41 (2.44%)	
occurrences (all)	3	1	
Dysuria	Additional description: Dysuria		
subjects affected / exposed	4 / 42 (9.52%)	0 / 41 (0.00%)	
occurrences (all)	4	0	
Musculoskeletal and connective tissue disorders			

Back pain subjects affected / exposed occurrences (all)	Additional description: Back pain		
	3 / 42 (7.14%)	3 / 41 (7.32%)	
	3	3	
Infections and infestations			
	Additional description: Nasopharyngitis		
	0 / 42 (0.00%)	4 / 41 (9.76%)	
	0	5	
	Additional description: Oral candidiasis		
	4 / 42 (9.52%)	7 / 41 (17.07%)	
	4	10	
	Additional description: Urinary tract infection		
	3 / 42 (7.14%)	1 / 41 (2.44%)	
	3	1	
Metabolism and nutrition disorders			
	Additional description: Hyponatraemia		
	3 / 42 (7.14%)	1 / 41 (2.44%)	
	6	1	
	Additional description: Hypokalaemia		
	18 / 42 (42.86%)	6 / 41 (14.63%)	
	34	11	
	Additional description: Hypocalcaemia		
	2 / 42 (4.76%)	3 / 41 (7.32%)	
	5	4	
	Additional description: Decreased appetite		
	11 / 42 (26.19%)	6 / 41 (14.63%)	
	14	8	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 April 2013	protocol version 2.0: change of sponsor, change from monocentric to multicentric
25 August 2016	protocol version 3.0: update of background information (epidemiology of PDAC), inclusion of secondary objective, enrollment of up to a maximum sample size of 112 patients, update of estimated treatment duration, clarifications
25 May 2021	protocol version 4.0: update of estimated treatment duration, study treatments leucovorin 200 mg/m ² added, COVID-19 related information, clarifications

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.

The study was planned for 112 patients. Due to the slow recruitment only 83 patients were randomized.

Notes: