



Clinical trial results:

Predictive value of in-vitro testing anti-cancer therapy sensitivity on tumoroids from patients with metastatic pancreatic cancer

Summary

EudraCT number	2018-003112-53
Trial protocol	DK
Global end of trial date	22 February 2023

Results information

Result version number	v1 (current)
This version publication date	18 January 2024
First version publication date	18 January 2024

Trial information

Trial identification

Sponsor protocol code	TIP
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03821870
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Vejle Hospital
Sponsor organisation address	Beriderbakken 4, Vejle, Denmark, 7100
Public contact	Clinical Trial Unit, Oncology, Vejle Hospital, karin.larsen1@rsyd.dk
Scientific contact	Clinical Trial Unit, Oncology, Vejle Hospital, karin.larsen1@rsyd.dk

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	02 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 February 2022
Global end of trial reached?	Yes
Global end of trial date	22 February 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The purpose of the present study is to investigate the predictive value of pretreatment in-vitro testing of drug sensitivity to patient-derived tumoroids.

Protection of trial subjects:

Antiemetics and other supportive treatment as necessary

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2018
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: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	2
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were included between February and October 2019.

Pre-assignment

Screening details:

Institution-based screening of all patients with non-resectable pancreatic cancer.

Period 1

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

Arms

Arm title	Precision cohort
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Arm description:

Patients with one histopathologic tumor type, pancreatic adenocarcinoma, are subdivided into treatment groups based on functional characteristics.

Arm type	Experimental
Investigational medicinal product name	Targeted treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

FOLFIRINOX .

Gemcitabine + Albumin-bound Paclitaxel.

Gemcitabine + Erlotinib.

Gemcitabine + Capecitabine.

Gemcitabine + Cisplatin.

Gemcitabine + docetaxel + capecitabine.

CAPOX: Day 1: Oxaliplatin 130 mg/m² IV. Days 1–14: Capecitabine 1,000 m

FOLFIRI: Day 1: irinotecan 180 mg/m² IV + leucovorin 400 mg/m² IV + 5-FU 400 mg/m² IV bolus and 5-FU 2,400 mg/m² IV for 46 h. Repeat every 2 weeks.

Olaparib: 300 mg orally twice daily.

Number of subjects in period 1^[1]	Precision cohort
Started	9
Completed	9

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 30 patients were planned. 12 were included. 9 started treatment of which none were evaluable for the primary endpoint.

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	9	9	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	2	2	
From 65-84 years	7	7	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	5	5	
Male	4	4	

End points

End points reporting groups

Reporting group title	Precision cohort
Reporting group description: Patients with one histopathologic tumor type, pancreatic adenocarcinoma, are subdivided into treatment groups based on functional characteristics.	

Primary: Response rate

End point title	Response rate ^[1]
End point description:	

End point type	Primary
End point timeframe: 6 months	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Not relevant since no patients were evaluable.

End point values	Precision cohort			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[2]			
Units: Number				

Notes:

[2] - No patients were evaluable.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Every 3-4 weeks.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4
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Reporting groups

Reporting group title	Overall group
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Only data on grade 3-5 events were collected.

Serious adverse events	Overall group		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 9 (66.67%)		
number of deaths (all causes)	8		
number of deaths resulting from adverse events	1		
Cardiac disorders			
Heart failure			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ventricular arrhythmia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			

subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infection			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Overall group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported