Clinical trial results:
Clinical trial with chemotherapy for patients with non-resectable, locally advanced pancreatic cancer and addition of chemo-radiotherapy for patients with borderline resectable pancreatic cancer.
DPSG - ”Danish Pancreatic cancer Study Group”

Summary

EudraCT number	2011-000703-40
Trial protocol	DK
Global end of trial date	15 February 2016

Results information

Result version number	v1 (current)
This version publication date	25 June 2021
First version publication date	25 June 2021
Summary attachment (see zip file)	Poster ASCO 2015 (FOLFIRINOX_poster_ASCO_2015.pptx)

Trial information

Trial identification

Sponsor protocol code	KFE10.08

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01397019
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	sdr. Boulevard 29, Odense, Denmark, 5000
Public contact	Research Secretary, Odense University Hospital, +45 65412921, mette.sander@rsyd.dk
Scientific contact	Research Secretary, Odense University Hospital, +45 65412921, mette.sander@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	Interim
Date of interim/final analysis	01 January 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the trial is to evaluate the effect of FOLFIRINOX in combination with chemo-radiotherapy in patients with borderline resectable pancreatic cancer (stage II or III).

Primary objective:
- 2 year survival

Protection of trial subjects:

The following measures were repeatedly assessed throughout the course of the study to monitor subject safety:
(1) Assessment of adverse events and serious adverse events,
(2) clinical laboratory tests,
(3) medical history,
(4) full review of body system through physical examination,
(5) vital signs assessment,
(6) Effect of chemotherapy

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 May 2011
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: 53
Worldwide total number of subjects	53
EEA total number of subjects	53

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)	24
From 65 to 84 years	29
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited between 06-08-2012 to 15-02-2016. Due logistical challenges data presented is on 53 patients. Remaining patients - will be incluided in the final publication

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	53
Number of subjects completed	53

Period 1

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

Blinding implementation details:

Not blinded

Arms

Arm title	Treatment

Arm description:

Per-protocol therapy

Arm type	Experimental
Investigational medicinal product name	FORFIRINOX
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

FOLFIRINOX (oxaliplatin 85 mg/m2, irinotecan 180 mg/m2, leucovorin 400 mg/m2, 5FU 400 mg/m2+ 2400 mg/m2) every 14 days

Number of subjects in period 1	Treatment
Started	53
Completed	53

Baseline characteristics

End points

End points reporting groups

Reporting group title	Treatment
Reporting group description: Per-protocol therapy	

Primary: two-year survivial

End point title	two-year survivial[1]
End point description:	
End point type	Primary
End point timeframe: data was calculated 1-jan-2016	

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: Please see attached poster for results and statistical analyses.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: percent				
number (confidence interval 46%)	46 (28 to 63)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Evaluated during therapy/on protocol	
Assessment type	Systematic
Dictionary used	
Dictionary name	CTCAE
Dictionary version	4
Reporting groups	
Reporting group title	Treatment
Reporting group description: Per-protocol therapy	

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 53 (3.77%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	2 / 53 (3.77%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 53 (100.00%)		
Congenital, familial and genetic disorders			
Nausea			
subjects affected / exposed	44 / 53 (83.02%)		
occurrences (all)	44		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	35 / 53 (66.04%)		
occurrences (all)	35		

Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	30 / 53 (56.60%)		
occurrences (all)	30		
Thrombocytopenia			
subjects affected / exposed	26 / 53 (49.06%)		
occurrences (all)	26		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	51 / 53 (96.23%)		
occurrences (all)	51		
Oral mucosal blistering			
subjects affected / exposed	24 / 53 (45.28%)		
occurrences (all)	24		
Pain			
subjects affected / exposed	38 / 53 (71.70%)		
occurrences (all)	38		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	33 / 53 (62.26%)		
occurrences (all)	33		
Diarrhoea			
subjects affected / exposed	44 / 53 (83.02%)		
occurrences (all)	44		
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	6 / 53 (11.32%)		
occurrences (all)	6		
Infections and infestations			
Infection			
subjects affected / exposed	23 / 53 (43.40%)		
occurrences (all)	23		

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