Clinical trial results: Proteomic profile analysis to classify advanced pancreatic adenocarcinoma patients for clinical outcome after treatment with PDXG (cisplatin, docetaxel, capecitabine, gemcitabine) or PEXG (cisplatin, epirubicin, capecitabine, gemcitabine) regimen

Summary

EudraCT number*	2009-013029-41
Trial protocol	PACT-13
Global end of trial date*	31Dec2013

Trial information

Trial identification	
Sponsor protocol code*	PACT-13
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors details*	
Sponsor organisation name	IRCCS Ospedale San Raffaele
Sponsor organisation address	Via Olgettina, 60, Milano, Italy, 20132
Public contact	reni.michele@hsr.it
Scientific contact	reni.michele@hsr.it

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

Results analysis stage	
Analysis stage*	Final
Date of interim/final analysis*	30Apr2013
Is this the analysis of the primary completion data?*	Yes
Global end of trial reached?*	Yes
Global end of trial date*	31Dec2013
Was the trial ended prematurely?	No

General information about the trial

1. To evaluate the predictive value of proteomic profiling on serum samples taken from patients with primary diagnosis of stage III and IV [15] advanced pancreatic adenocarcinoma who receive first-line chemotherapy with either PDXG (Cisplatin, Docetaxel, Gemcitabine, Capecitabine) or PEXG (Cisplatin, Epirubicin, Gemcitabine, Capecitabine) regimen.
2. To evaluate in a population of patients with pancreatic cancer the epidemiology of the spectrum which was predictive of response to anti-EGFR agents in lung cancer.

Actual start date of recruitment*	19Aug2009
Long term follow-up planned*	NO
If Yes, rationale:	Safety Efficacy Ethical reason Regulatory reason Scientific research
Duration	-
Independent data monitoring committee (IDMC) involvement?*	No
Protection of trial subjects*:	Yes
Background therapy:	No
Evidence for comparator:	

Population of trial subjects

Subjects enrolled per country

Country:	Italy
Planned number of subjects	100
Actual Number of subjects enrolled*	94
Worldwide total number of subjects	0
EEA total number of subjects	94 (only in Italy)

Subjects enrolled per age group

In utero*	N/A
Preterm newborn - gestational age < 37wks*	N/A
Newborns (0-27 days)*	N/A
Infants and toddlers (28 days-23months)*	N/A
Children (2-11 years)*	N/A
Adolescents (12-17 years)*	N/A
Adults (18-64 years)*	61
From 65 to 84 years*	33
85 years and over*	0

Subject disposition

Recruitment details:

Enrollment from 19Aug2009 to 06Nov2012 in 1 clinical center

Pre-assignment - *Screening details*:

The study population consists of adult Caucasian patients (≥ 18 years old) affected by pancreatic cancer

Inclusion criteria

- Patients with cytological or histological diagnosis of pancreatic adenocarcinoma at stage III or IV who are candidate to receive upfront chemotherapy according to PDXG or PEXG regimen.

Period 1	
Period title*	*Overall Trial*
Is this the baseline period?	No
Allocation method*	Not applicable
Blinding used*	

Arms

Arm title*	**PROTEOMIC PROFILE**
Arm description:	serum proteomic profile in patients with cytological or histological diagnosis of pancreatic adenocarcinoma at stage III or IV who are candidate to receive upfront chemotherapy according to PDXG or PEXG regimen
Arm type*	Not applicable
Investigational medicinal product name*	Not applicable
Investigational medicinal product code	
Other name	
Pharmaceutical forms*	
Routes of administration*	
Dosage and administration details*	

Number of subjects in period	**PROTEOMIC PROFILE**	
Started*	96	
Completed*	94	
Subject non-completion reason (if applicable)		
AE, non fatal	0	
AE, fatal	0	
Consent withdrawn by subject	2	
Lack of efficacy	0	
Lost to follow up	0	
Physician decision	0	
Pregnancy	0	
Protocol Deviation		
Other		

Baseline characteristics

Reporting groups* Overall cohort	
Reporting group title*	**PROTEOMIC PROFILE**
Number of subjects at the baseline*	94 patients

Reporting group description: *You can report per arm in the baseline period or for the overall baseline period*

Subject analysis sets

Add a subject analysis set if you wish to report on groups different from the reporting group defined above (repeat if applicable)

Subject analysis set title*	
Subject analysis set type*	
Subject analysis set description*	
Number of subjects in subjects analysis set*	

Age characteristics*

Complete either the age categorical, age continuous or complete both these characteristics in order to collect values for the reporting groups and optionally the subject analysis sets.

	Characteristic title*	Units*	Age categories*
Age categorical			

	Characteristic title*	Units*	Central tendency*	Dispersion type*
Age continuous	Overall cohort	Years	Median 61 years	full range (min-max) 38-75 years

Gender characteristics*

	Characteristic title*	Units*	Gender categories*
Gender categorical	Gender	Count	Female: 44 Male: 50

Study specific characteristics

	Characteristic title*	Units *	Categories*	Number of subject for each categories
Study specific categorical				
Study specific categorical				
Study specific categorical				
Study specific categorical				
Study specific categorical				

End points

Add subject analysis set if you wish to report on groups different form reporting groups defined above

Subject analysis set title*	ALL PATIENTS
Subject analysis set type*	Per protocol
Subject analysis set description*	Predictive value of proteomic profiling on serum samples taken from patients with primary diagnosis of stage III and IV [15] advanced pancreatic adenocarcinoma who receive first-line chemotherapy with either PDXG (Cisplatin, Docetaxel, Gemcitabine, Capecitabine) or PEXG (Cisplatin, Epirubicin, Gemcitabine, Capecitabine) regimen
Number of subject in subject analysis set *	94

End points definitions

End point title*	**Correlation between proteomic profile and Progression free Survival (PFS)**	
		Values
Countable or measurable?*	Measurable	Median PFS
If countable, Countable units*:		
If measurable, Measurable units*	Months	
Measure type*:	Median	
Precision/dyspersion type*	95% Confidence Interval (CI)	

End point type*	Secondary

End point timeframe*: From start of therapy to PD

End point title*	**Correlation between proteomic profile and Overall survival (OS)**	
		Values
Countable or measurable?*	Measurable	Median overall survival
If countable, Countable units*:		
If measurable, Measurable units*	Months	
Measure type*:	Median	
Precision/dyspersion type*	95% Confidence Interval (CI)	

End point type*	Secondary

End point timeframe*: From start of therapy to death from any cause

Use categories only if the data for the end point can be categorized

Category title

Specify the groups of subjects applicable to this end point

Reporting groups*			
Period			

Arms			
subject analysis sets			

Adverse events

Adverse events information

Timeframe for reporting adverse events*: *Enter the time point(s) or time period for AE assessment*
Only SAE, from start of treatment until 28 days after the last dose

Adverse event reporting additional description	
Assessment type*	Non Systematic
Frequency threshold for reporting non-serious adverse events*	

Dictionary used

Dictionary name*	CTCAE
Dictionary version*	3.0

Adverse events reporting group definition

Use arms from baseline period as reporting groups
OR

Reporting group title*:

For this reporting group, provide the following totals:

Subject exposed*	
Subjects affected by non -SAE*	
Total number of deaths (all causes)*	
Total number of deaths resulting from adverse event*	

Serious adverse event details and values

System organ class*: Hemorrhage/Bleeding, Gastrointestinal, Neurology

Event term*: Hemorrhagic shock, Intestinal sub-occlusion; Stroke

Values for serious adverse event per reporting group *

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number	Occurrences causally related to treatment number	Fatalities number	Fatalities causally related to treatment number
PEXG	3 (3%)	94	3 (3%)	0	2 (2%)	0

Non - Serious adverse event details and values

System organ class*: N/A

Event term*: N/A

Values for non-serious adverse event per reporting group*

Threshold for non-serious adverse event reporting is:

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol*? No

Date	Amendment

Notes:

Interruptions (globally)

Were there any global interruptions to the trial*? NO

If Yes, Interruption date

Interruption description

Limitations and caveats

None reported

Online references

None