Clinical trial results:
Phase II trial with Cetuximab and Irinotecan (CetIri) for patients with platinum resistant esofagus- or gastric cancer

Summary

EudraCT number	2008-006168-12
Trial protocol	DK
Global end of trial date	25 October 2013

Results information

Result version number	v1 (current)
This version publication date	19 March 2021
First version publication date	19 March 2021
Summary attachment (see zip file)	SAE list (SAE LIST English 030321.DOC)

Trial information

Trial identification

Sponsor protocol code	08.14

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	J. B. Winsløws Vej 4, entrance 140, basement, Odense C, Denmark, 5000
Public contact	Ida Coordt Elle, Odense University Hospital, +45 29335922, ida.coordt.elle@rsyd.dk
Scientific contact	Per Pfeiffer, Odense University Hospital, +45 26283844, per.pfeiffer@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	03 March 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objektives are responserate and time to progression.

Protection of trial subjects:

Administration of pre-medication to minimize adverse events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 January 2009
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	Denmark: 71
Worldwide total number of subjects	71
EEA total number of subjects	71

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)	40
From 65 to 84 years	31
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Jan. 2009-Feb. 2013

Pre-assignment

Screening details:

Phase II trial with Cetuximab and Irinotecan (CetIri) for patients with platinum-resistent esophagus- or stomach-cancer.
Patients with either adenocarcinoma or planocellular carcinoma can be included in the trial.

Period 1

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

Arms

Arm title	Experimental

Arm description:

Cetuximab+Irinotecan

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg/m2 i.v. on day 1 every two weeks.

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

Dosage and administration details:

180 mg/m2 i.v. on day 1 every two weeks.

Number of subjects in period 1	Experimental
Started	71
Completed	71

Baseline characteristics

Reporting groups	
Reporting group title	Trial

Reporting group description: -

Reporting group values	Trial	Total	
Number of subjects	71	71	
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)	40	40	
From 65-84 years	31	31	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	15	15	
Male	56	56	

Subject analysis sets	
Subject analysis set title	Patients
Subject analysis set type	Full analysis

Subject analysis set description:

Full analysis of all patients included in Odense.

Reporting group values	Patients		
Number of subjects	71		
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)	40		
From 65-84 years	31		
85 years and over	0		

Gender categorical Units: Subjects			
Female	15		
Male	56		

End points

End points reporting groups

Reporting group title	Experimental
Reporting group description: Cetuximab+Irinotecan	
Subject analysis set title	Patients
Subject analysis set type	Full analysis
Subject analysis set description: Full analysis of all patients included in Odense.	

Primary: Progression-free survival

End point title	Progression-free survival[1]
End point description:	
End point type	Primary
End point timeframe: 24 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: No statistical analysis has been performed on the 71 patients from Odense.
Analysis of 63 patients included in Odense and Aalborg has been performed in the attached publication.

End point values	Experimental	Patients		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	71	71		
Units: months				
median (confidence interval 95%)	2.8 (1.8 to 3.5)	2.8 (1.8 to 3.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information
Timeframe for reporting adverse events: Last treatment + 30 days.
Adverse event reporting additional description: Please refer to the attached SAE list (attached as Summary) and publication.

Systematic

subjects affected / exposed	1 / 71 (1.41%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Respiratory, thoracic and mediastinal disorders			
Pseudomonas infection			
subjects affected / exposed	1 / 71 (1.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Dyspnoea			
subjects affected / exposed	1 / 71 (1.41%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 1		

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

Non-serious adverse events	Patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 71 (28.17%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	9 / 71 (12.68%)		
occurrences (all)	15		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	8 / 71 (11.27%)		
occurrences (all)	8		
Nausea			
subjects affected / exposed	3 / 71 (4.23%)		
occurrences (all)	6		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/22244801