Clinical trial results:
PHASE II TRIAL OF PALLIATIVE EPIRUBICIN, OXALIPLATIN & CAPECITABINE (EOX) CHEMOTHERAPY COMBINED WITH OMEGA-3 FISH OIL INFUSION (OMEGAVEN) IN PATIENTS WITH OESOPHAGO-GASTRIC CARCINOMA

Summary

EudraCT number	2011-003950-24
Trial protocol	GB
Global end of trial date	31 July 2016

Results information

Result version number	v1 (current)
This version publication date	20 March 2019
First version publication date	20 March 2019

Trial information

Trial identification

Sponsor protocol code	EOX1.4

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01870791
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospitals of Leicester NHS Trust
Sponsor organisation address	Infirmary Square, Leicester, United Kingdom, LE1 5WW
Public contact	Prof David Bowrey, University Hospitals of Leicester NHS Trust, djb57@le.ac.uk
Scientific contact	Prof David Bowrey, University Hospitals of Leicester NHS Trust, djb57@le.ac.uk

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	01 May 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 July 2014
Global end of trial reached?	Yes
Global end of trial date	31 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety profile of intravenous omega-3 fatty acid emulsion combined with standard palliative chemotherapy (EOX) in patients with incurable gastric or oesophageal carcinoma.

Protection of trial subjects:

Review by study sponsor of safety profile of treatment after each participant

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 March 2012
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	United Kingdom: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	11
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment ran between 05/01/2012 and 07/31/2013

Pre-assignment

Screening details:

The study recruited adult patients referred to the University Hospitals of Leicester NHS Trust, UK with confirmed diagnoses of inoperable esophageal, gastroesophageal junctional or gastric adenocarcinoma, eligible for palliative chemotherapy. Treatment intent was determined at the weekly multi-disciplinary team meeting by the clinical team

Pre-assignment period milestones

Number of subjects started	21
Number of subjects completed	21

Period 1

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

Arms

Arm title	Palliative chemotherapy and Omegaven

Arm description:

Participants received palliative chemotherapy with intravenous epirubicin (50 mg/m2) and oxaliplatin (130 mg/m2) every 21 days and oral capecitabine (1,250 mg/m2) daily for 21 days, in addition to Omegaven® as a once weekly at a rate of 2 ml/kg body weight for 4 hr

Arm type	Experimental
Investigational medicinal product name	Omegaven
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion for infusion
Routes of administration	Intravenous drip use

Dosage and administration details:

Omegaven®was infused once weekly at a rate of 2 ml/kg body weight for 4 hr

Number of subjects in period 1	Palliative chemotherapy and Omegaven
Started	21
Completed	20
Not completed	1
Physician decision	1

Baseline characteristics

Reporting groups

Reporting group title	Palliative chemotherapy and Omegaven

Reporting group description:

Participants received palliative chemotherapy with intravenous epirubicin (50 mg/m2) and oxaliplatin (130 mg/m2) every 21 days and oral capecitabine (1,250 mg/m2) daily for 21 days, in addition to Omegaven® as a once weekly at a rate of 2 ml/kg body weight for 4 hr

Reporting group values	Palliative chemotherapy and Omegaven	Total	
Number of subjects	21	21	
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	67		
full range (min-max)	47 to 80	-	
Gender categorical Units: Subjects			
Female	5	5	
Male	16	16	

Subject analysis sets

Subject analysis set title	Palliative chemotherapy and Omegaven
Subject analysis set type	Full analysis

Subject analysis set description:

Patients receiving palliative EOX chemotherapy and weekly Omegaven infusion

Reporting group values	Palliative chemotherapy and Omegaven		
Number of subjects	21		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years median full range (min-max)	 67 47 to 80		
Gender categorical Units: Subjects			
Female Male	5 16		

End points

End points reporting groups

Reporting group title	Palliative chemotherapy and Omegaven

Reporting group description:

Participants received palliative chemotherapy with intravenous epirubicin (50 mg/m2) and oxaliplatin (130 mg/m2) every 21 days and oral capecitabine (1,250 mg/m2) daily for 21 days, in addition to Omegaven® as a once weekly at a rate of 2 ml/kg body weight for 4 hr

Subject analysis set title	Palliative chemotherapy and Omegaven
Subject analysis set type	Full analysis

Subject analysis set description:

Patients receiving palliative EOX chemotherapy and weekly Omegaven infusion

Primary: Safety profile of Omegaven

End point title	Safety profile of Omegaven[1]

End point description:

To assess the effect, tolerability (side effects) and feasibility of use (number of participants requiring dose delays and/or treatment withdrawal)

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: This was a proof of principle trial, primarily assessing the safety profile of Omegaven in this patient participant group.

End point values	Palliative chemotherapy and Omegaven			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: adverse events	20			

Statistical analyses

No statistical analyses for this end point

Secondary: Radiological response rate

End point title	Radiological response rate

End point description:

Objective response rate as assessed by RECIST criteria

End point type	Secondary

End point timeframe:

6 months

End point values	Palliative chemotherapy and Omegaven			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: RECIST criteria	15			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Any adverse event observed during the study period was reported to the study sponsor

Adverse event reporting additional description:

Adverse events were reported according to the CTCAE v 4.03

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.03

Reporting groups

Reporting group title	Palliative chemotherapy and Omegaven

Reporting group description:

Participants received palliative chemotherapy with intravenous epirubicin (50 mg/m2) and oxaliplatin (130 mg/m2) every 21 days and oral capecitabine (1,250 mg/m2) daily for 21 days, in addition to Omegaven® as a once weekly at a rate of 2 ml/kg body weight for 4 hr

Serious adverse events	Palliative chemotherapy and Omegaven		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Palliative chemotherapy and Omegaven		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 20 (85.00%)		
Immune system disorders			
Grade 3 or 4 chemotherapy related toxicities	Additional description: All grade 3 or 4 chemotherapy related toxicities were recorded, and these are presented below (the commonest was neutropenia)		
subjects affected / exposed	17 / 20 (85.00%)		
occurrences (all)	17		

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/30711967

http://www.ncbi.nlm.nih.gov/pubmed/27342748