Clinical trial results:
behandling af patienter med avanceret rectumcancer med capecitabin og oxaliplatin før under og efter kurativt intenderet strålebehandling, samt tillæg af cetuximab til patienter der er K-RAS vild-type

Summary

EudraCT number	2009-010976-94
Trial protocol	DK
Global end of trial date	11 January 2017

Results information

Result version number	v1 (current)
This version publication date	18 December 2019
First version publication date	18 December 2019

Trial information

Trial identification

Sponsor protocol code	gi0901

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00964457
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Herlev Hospital
Sponsor organisation address	Herlev Ringvej 75, Herlev, Denmark, 2730
Public contact	Finn Ole Larsen, Department of Oncolocgy Herelv Hospital, +45 38682329, finn.ole.larsen@regionh.dk
Scientific contact	Finn Ole Larsen, Department of Oncolocgy Herelv Hospital, +45 38682329, finn.ole.larsen@regionh.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	11 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 January 2017
Global end of trial reached?	Yes
Global end of trial date	11 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

evaluate response to the treatment

Protection of trial subjects:

Eligibility criteria and standard safety monitoring

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	26
From 65 to 84 years	26
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patient were recruited at single site (Herlev Hospital) in Denmark from Aug 2009 to Jun 2012

Pre-assignment

Screening details:

Rectum cancer T3 or T4, performance status 0-1

Period 1

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

Blinding implementation details:

open label trial without comparator arm

Arms

Arm title	Study treatment

Arm description:

Capecitabine + Oxaliplatin + radiation

Arm type	Experimental
Investigational medicinal product name	Capecitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

650 mg /m2 x 2 daily (16 weeks)

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

Dosage and administration details:

85 mg/m2 every 2 weeks (6 weeks before and 4 weeks after radiation), during radiation the dose was 50 mg/m2 every week (6 weeks)

Number of subjects in period 1	Study treatment
Started	52
Completed	51
Not completed	1
Adverse event, serious fatal	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	52	52	
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	65		
full range (min-max)	41 to 77	-	
Gender categorical Units: Subjects			
Female	21	21	
Male	31	31	

End points

End points reporting groups

Reporting group title	Study treatment
Reporting group description:	
Capecitabine + Oxaliplatin + radiation	

Primary: Response rate

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

End point type	Primary
End point timeframe:	
At end of treatment (16 weeks)	

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: Phase 2 design of trial, without comperator

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: number of patients				
CR	0			
PR	34			
SD	2			
PD	0			
Not assesable	16			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival rate

End point title	Overall survival rate
End point description:	

End point type	Secondary
End point timeframe:	
5 years after treatment start	

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: percent	65			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Treatment start to 30 days after last treatment	
Assessment type	Systematic
Dictionary used	
Dictionary name	NCI-CTCAE
Dictionary version	3
Reporting groups	
Reporting group title	Study treatment
Reporting group description: Capecitabine + Oxaliplatin + radiation	

Serious adverse events	Study treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 52 (1.92%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	1 / 52 (1.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

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

Non-serious adverse events	Study treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 52 (44.23%)		
Nervous system disorders			
Neurotoxicity	Additional description: grade 3		
subjects affected / exposed	5 / 52 (9.62%)		
occurrences (all)	5		
General disorders and administration site conditions			
Fatigue	Additional description: grade 3		

subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		
Gastrointestinal disorders			
Diarrhoea	Additional description: grade 3 and grade 4		
subjects affected / exposed	12 / 52 (23.08%)		
occurrences (all)	12		
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome	Additional description: grade 3		
subjects affected / exposed	3 / 52 (5.77%)		
occurrences (all)	3		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

NA

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27743742