Clinical trial results:
Epirubicin as 2nd line treatment to patients with TOP2A gene amplified and oxaliplatin refractory metastatic colerectal cancer

Summary

EudraCT number	2013-001648-79
Trial protocol	DK
Global end of trial date	31 December 2017

Results information

Result version number	v1 (current)
This version publication date	31 January 2020
First version publication date	31 January 2020
Summary attachment (see zip file)	Epirubicin BMC Cancer (BMC cancer 2016 CRC Epirubicin.pdf)

Trial information

Trial identification

Sponsor protocol code	KFE13.10

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	JB Winslowsvej 4, Odense C, Denmark, 5000
Public contact	Per Pfeiffer, Odense University Hospital, +45 65413834, per.pfeiffer@rsyd.dk
Scientific contact	Per Pfeiffer, Odense University Hospital, +45 65413834, 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	Interim
Date of interim/final analysis	31 December 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Progression-free survival

Protection of trial subjects:

Progression-free survival

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 September 2013
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: 6
Worldwide total number of subjects	6
EEA total number of subjects	6

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)	5
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

To be eligible for inclusion, patients must provide written
informed consent, age of 18 years, WHO performance status 0–2,
a life expectancy of at least 3 months, histologically verified, non-resectable,
oxaliplatin resistant mCRC, and the TOP2A/CEN-17 ratio and this ratio
has to be ≥ 1.5.
Periode: 02.09.13-31-12-17

Pre-assignment

Screening details:

To be eligible for inclusion, patients must provide written
informed consent, age of 18 years, WHO performance status 0–2,
a life expectancy of at least 3 months, histologically verified, non-resectable,
oxaliplatin resistant mCRC, and the TOP2A/CEN-17 ratio and this ratio
has to be ≥ 1.5.

Period 1

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

Blinding implementation details:

Non

Arms

Arm title	No randomization

Arm description: -

Arm type	Treatment
Investigational medicinal product name	Epirubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

900 mg /m2 every 3th week

Number of subjects in period 1	No randomization
Started	6
Completed	6

Baseline characteristics

End points

End points reporting groups

Reporting group title	No randomization

Reporting group description: -

Primary: Progression-free survival

End point title	Progression-free survival[1]

End point description:

End point type	Primary

End point timeframe:

From inclusion to progressive disease

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 is a single arm study - statistic analysis is described in the article.

End point values	No randomization			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: months				
median (full range (min-max))	1 (0 to 24)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 02.09.2013-31.12.2017	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.0

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: We do not experience any non-SAE in the few patients included.

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.

Early termination due to slow recruitment.

Notes: