Clinical trial results:
Phase II study with temozolomide and capecitabine for patients with refractory colorectal cancer.

Summary

EudraCT number	2012-002327-15
Trial protocol	DK
Global end of trial date	21 September 2016

Results information

Result version number	v1 (current)
This version publication date	11 March 2021
First version publication date	11 March 2021
Summary attachment (see zip file)	TEM poster (TEMPoster (003).pptx)

Trial information

Trial identification

Sponsor protocol code	KFE12.05

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	01 September 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate a new treatment regimen for pre-treated patients with metastatic colorectal cancer.

Protection of trial subjects:

Administration of pre-medication to minimize nausea.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 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: 42
Worldwide total number of subjects	42
EEA total number of subjects	42

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)	14
From 65 to 84 years	28
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

29.05-2013-08.10.2015

Pre-assignment

Screening details:

Pre-treated patients with KRAS-mutated metastatic colorectal cancer.

Period 1

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

Arms

Arm title	Experimental

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

150 mg/m2 on days 10-14 of four-week-cycles.

Investigational medicinal product name	Capecitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2000 mg/m2 on days 1-14 during four-week-cycles.

Number of subjects in period 1	Experimental
Started	42
Completed	42

Baseline characteristics

Reporting groups

Reporting group title	Trial period

Reporting group description: -

Reporting group values	Trial period	Total	
Number of subjects	42	42	
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)	14	14	
From 65-84 years	28	28	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	19	19	
Male	23	23	

Subject analysis sets

Subject analysis set title	Patients
Subject analysis set type	Full analysis

Subject analysis set description:

Analysis of all patients.

Reporting group values	Patients		
Number of subjects	42		
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)	14		
From 65-84 years	28		
85 years and over	0		

Gender categorical Units: Subjects			
Female	19		
Male	23		

End points

End points reporting groups

Reporting group title	Experimental
Reporting group description: -	
Subject analysis set title	Patients
Subject analysis set type	Full analysis
Subject analysis set description: Analysis of all patients.	

Primary: Progression-free survival

End point title	Progression-free survival[1]
End point description:	
End point type	Primary
End point timeframe: 12 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: Please see attached summary for further details.

End point values	Experimental	Patients		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	42	42		
Units: months				
median (confidence interval 95%)	2.1 (1.1 to 3.4)	2.1 (1.1 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Last treatment + 30 days.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.1
Reporting groups	
Reporting group title	Patients

Reporting group description: -

Serious adverse events	Patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 42 (0.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 42 (11.90%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 42 (7.14%)		
occurrences (all)	3		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences (all)	1		
Nausea			

subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 2		

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