



## Clinical trial results:

### Phase II study with cetuximab, irinotecan and sunitinib (CIS) for patients with treatment resistant colorectal cancer.

#### Summary

EudraCT number	2007-004232-22
Trial protocol	DK
Global end of trial date	07 May 2009

#### Results information

Result version number	v1 (current)
This version publication date	18 March 2021
First version publication date	18 March 2021

#### Trial information

##### Trial identification

Sponsor protocol code	SIC
-----------------------	-----

##### 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. Winsløvs Vej 2, 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 June 2010
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	07 May 2009
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To investigate the combination of Cetuximab, Irinotecan and Sunitinib (CIS or SIC) for treatment of patients with treatment-resistant colorectal cancer.

Protection of trial subjects:

Administration of pre-medication to minimize adverse reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 January 2008
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: 55
Worldwide total number of subjects	55
EEA total number of subjects	55

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	15
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

November 2007-January 2009.

Follow-up until disease progression.

Expected number of patients: 55.

### Pre-assignment

Screening details:

In Denmark, approximately 150 patients per year will be of adequate performance status to be offered 3rd line chemotherapy. Before the introduction of Cetuximab and Irinotecan, there was no 3rd line treatment to offer these patients. Adding Sunitinib to the regimen is expected to prolong PFS and thereby quality of life for these patients.

### 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:

Cetuximab 500 mg/m<sup>2</sup> i.v. day 1 every 2 weeks.

Irinotecan 180 mg/m<sup>2</sup> i.v. day 1 every 2 weeks.

Sunitinib 25 mg p.o. daily for 4 weeks and afterwards 37.5 mg daily.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution and suspension for suspension for injection in pre-filled syringe
Routes of administration	Intravenous use

Dosage and administration details:

500 mg/m<sup>2</sup> on day 1 every two weeks.

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

Dosage and administration details:

180 mg/m<sup>2</sup> on day 1 every two weeks.

Investigational medicinal product name	Sunitinib
Investigational medicinal product code	
Other name	Sutent
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

25 mg per day for 4 weeks and then 37.5 mg per day.

<b>Number of subjects in period 1</b>	Experimental
Started	55
Completed	55

## Baseline characteristics

### Reporting groups

Reporting group title	Trial period
Reporting group description: -	

Reporting group values	Trial period	Total	
Number of subjects	55	55	
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	15	15	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Male	30	30	
Female	25	25	

### Subject analysis sets

Subject analysis set title	Patients
Subject analysis set type	Full analysis
Subject analysis set description:	
All patients in the study.	

Reporting group values	Patients		
Number of subjects	55		
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	15		
85 years and over	0		

Gender categorical			
Units: Subjects			
Male	30		
Female	25		

## End points

### End points reporting groups

Reporting group title	Experimental
Reporting group description: Cetuximab 500 mg/m <sup>2</sup> i.v. day 1 every 2 weeks. Irinotecan 180 mg/m <sup>2</sup> i.v. day 1 every 2 weeks. Sunitinib 25 mg p.o. daily for 4 weeks and afterwards 37.5 mg daily.	
Subject analysis set title	Patients
Subject analysis set type	Full analysis
Subject analysis set description: All patients in the study.	

### Primary: Progression-free survival

End point title	Progression-free survival <sup>[1]</sup>
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: The study was not deemed publishable; therefore no thorough analysis of the data was performed.	

End point values	Experimental	Patients		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20		
Units: months				
median (confidence interval 95%)	3 (0 to 8)	3 (0 to 8)		

### 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	20 / 55 (36.36%)		
number of deaths (all causes)	19		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 55 (1.82%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Febrile neutropenia			
subjects affected / exposed	2 / 55 (3.64%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Febrile infection			
subjects affected / exposed	5 / 55 (9.09%)		
occurrences causally related to treatment / all	5 / 5		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Thrombosis			
subjects affected / exposed	3 / 55 (5.45%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		



Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	2 / 55 (3.64%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	3 / 55 (5.45%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	1 / 55 (1.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infection			
subjects affected / exposed	4 / 55 (7.27%)		
occurrences causally related to treatment / all	4 / 4		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	Patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	45 / 55 (81.82%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	40 / 55 (72.73%)		
occurrences (all)	40		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	18 / 55 (32.73%)		
occurrences (all)	18		
Nausea			
subjects affected / exposed	20 / 55 (36.36%)		
occurrences (all)	24		



## **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