



## Clinical trial results:

### Phase II trial of Cetuximab in combination with chemotherapy (Carboplatinum and Navelbine) for patients with platinum-resistant head- and neckcancer

#### Summary

EudraCT number	2009-013878-40
Trial protocol	DK
Global end of trial date	01 June 2012

#### 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	09.08
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##### 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 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	15 June 2012
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 June 2012
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of the trial is to find a new effective second line treatment regimen for patients with locally advanced or metastatic head- and neck-cancer, who progressed during or after first-line treatment with cisplatin.

Primary objective(s):

Response rate (RR) and progression-free survival (PFS)

Protection of trial subjects:

Pre-medication administered to minimize nausea.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 January 2010
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: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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	0

85 years and over	0
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## Subject disposition

### Recruitment

Recruitment details:

Recruitment for 24 months (01.01.2010-31.12.2011)

### Pre-assignment

Screening details:

Patients with histologically confirmed head- and neck-cancer, where curatively intended treatment is not possible.

### Period 1

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

### Arms

Arm title	Experimental
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Arm description:

Cetuximab, Carboplatin, and Vinorelbine .

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg/m<sup>2</sup> i.v. day 1 every other week.

Investigational medicinal product name	Carboplatin
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:

AUC = 2.4 i.v. on day 1 every other week.

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

Dosage and administration details:

20 mg/m<sup>2</sup> i.v. on day 1 every other week.

<b>Number of subjects in period 1</b>	Experimental
Started	5
Completed	5

## Baseline characteristics

### Reporting groups

Reporting group title	Trial
Reporting group description: -	

Reporting group values	Trial	Total	
Number of subjects	5	5	
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)	5	5	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	1	1	
Male	4	4	

### Subject analysis sets

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

Reporting group values	Patients		
Number of subjects	5		
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)	5		
From 65-84 years	0		
85 years and over	0		

Gender categorical			
Units: Subjects			
Female	1		
Male	4		

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## End points

### End points reporting groups

Reporting group title	Experimental
Reporting group description: Cetuximab, Carboplatin, and Vinorelbine .	
Subject analysis set title	Patients
Subject analysis set type	Full analysis
Subject analysis set description: All patients included in the trial.	

### 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: It makes no sense to perform a statistical analysis on a study of only five patients. The study ended because not enough patients could be recruited.

End point values	Experimental	Patients		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	5		
Units: months				
median (confidence interval 95%)	2 (1 to 9)	2 (1 to 9)		

### 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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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### Reporting groups

Reporting group title	Patients
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Reporting group description: -

Serious adverse events	Patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events	0		
Immune system disorders			
Allergic reaction to excipient			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess oral			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)		
General disorders and administration site conditions			
Nail disorder			

subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Rash subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Dizziness subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 2		
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 3		
Respiratory, thoracic and mediastinal disorders Apnoea subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported