Clinical trial results:
Concomitant Tarceva® and irradiation in patients in local-regionally advanced non-small cell lung cancer. A phase II study

Summary

EudraCT number	2008-008921-30
Trial protocol	DK
Global end of trial date	04 February 2017

Results information

Result version number	v1 (current)
This version publication date	05 November 2021
First version publication date	05 November 2021

Trial information

Trial identification

Sponsor protocol code	09.02

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 2, entrance 140, basement, Odense C, Denmark, 5000
Public contact	Ida Coordt Elle, Odense University Hospital J. B. Winsløws vej 2, entrance 140, basement 5000 Odense C, +45 29335922, ida.coordt.elle@rsyd.dk
Scientific contact	Olfred Hansen, Odense University Hospital J. B. Winsløws vej 2, entrance 140, basement 5000 Odense C, +45 2424 1588, Olfred.Hansen@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	31 December 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the phase II trial is to examine Tarceva concomitant with curatively intended irradiation 66 Gy (2 Gy x 33 F, 5 F per week)

Primary endpoint
- Local failure free survival at 9 months after start of radiotherapy evaluated at CT scan

Protection of trial subjects:

Patients were monitored closely and (pre-)medication for AEs was administered.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 June 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	2

From 65 to 84 years	11
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Patients with NCSLC stage IIB-IIIB without pleural fluid, who are candidates for curatively intended radiotherapy and concomitant Tarceva.

Pre-assignment

Screening details:

Patients with histologically or cytologically confirmed locally advanced NSCLC stage IIB-IIIB without pleural fluid.
ECOG PS 0-2.
ALAT ≤ 2 x ULN.
Serum bilirubin ≤ 1.4 x ULN.

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	TARLAL

Arm description:

Radiotherapy with concomitant Tarceva.

Arm type	Experimental
Investigational medicinal product name	Tarceva
Investigational medicinal product code	Erlotinib
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tarceva 150 mg per day.

Investigational medicinal product name	Curatively intended radiotherapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pharmaceutical dose form not applicable
Routes of administration	Route of administration not applicable

Dosage and administration details:

66 Gy (2 Gy x 33 F, 5 F per week).

Number of subjects in period 1	TARLAL
Started	15
Completed	15

Baseline characteristics

Reporting groups	
Reporting group title	Trial period
Reporting group description: All patients	

Reporting group values	Trial period	Total	
Number of subjects	15	15	
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)	2	2	
From 65-84 years	11	11	
85 years and over	2	2	
Gender categorical Units: Subjects			
Female	6	6	
Male	9	9	

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

Reporting group values	Patients		
Number of subjects	15		
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)	2		
From 65-84 years	11		
85 years and over	2		

Gender categorical Units: Subjects			
Female	6		
Male	9		

End points

End points reporting groups

Reporting group title	TARLAL
Reporting group description: Radiotherapy with concomitant Tarceva.	
Subject analysis set title	Patients
Subject analysis set type	Full analysis
Subject analysis set description: All patients in trial.	

Primary: Overall survival

End point title	Overall survival[1]
End point description:	
End point type	Primary

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 days after last treatment	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0
Reporting groups	
Reporting group title	Patients

Reporting group description: -

Serious adverse events	Patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 15 (60.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Dehydration			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Ileus			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Endocrine disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonitis			
subjects affected / exposed	6 / 15 (40.00%)		
occurrences causally related to treatment / all	6 / 6		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fungal infection	Additional description: in the mouth		
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 15 (100.00%)		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	7 / 15 (46.67%)		
occurrences (all)	7		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 15 (46.67%)		
occurrences (all)	7		
Pneumonitis			
subjects affected / exposed	6 / 15 (40.00%)		
occurrences (all)	6		

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.

The trial ended because of insufficient patient inclusion.

Notes: