



## Clinical trial results:

**Etude de phase II évaluant un traitement par cisplatine et vinorelbine orale administrés de façon hebdomadaire et radiothérapie concomitante chez le sujet âgé indépendant atteint de cancer broncho-pulmonaire non à petites cellules localisé non opérable.**

### Summary

EudraCT number	2009-012413-21
Trial protocol	FR
Global end of trial date	17 February 2015

### Results information

Result version number	v1 (current)
This version publication date	28 May 2021
First version publication date	28 May 2021
Summary attachment (see zip file)	Suammary results (raccosa_resume rapport final.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	I08011
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01029678
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	CHU de Limoges
Sponsor organisation address	2 Avenue Martin Luther King -, Limoges , France, 87042
Public contact	Pr Alain VERGNENEGRE Pricipal Investigator, CHU de Limoges, 33 555056149, alain.vergnenegre@chu-limoges.fr
Scientific contact	Pr Alain VERGNENEGRE Pricipal Investigator, CHU de Limoges, 33 555056149, alain.vergnenegre@chu-limoges.fr

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:

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**Results analysis stage**

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Analysis stage	Final
Date of interim/final analysis	06 January 2018
Is this the analysis of the primary completion data?	No

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Global end of trial reached?	Yes
Global end of trial date	17 February 2015
Was the trial ended prematurely?	No

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Notes:

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**General information about the trial**

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Main objective of the trial:

Assessment of the Safety of a cisplatine/vinorelbine traitment

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Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed. All patients gave their consent after full information.

Moreover, a DSMB ensured the ethical and safety oversight of the trial.

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Background therapy: -

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Evidence for comparator: -

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Actual start date of recruitment	19 July 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

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Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

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Country: Number of subjects enrolled	France: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

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Notes:

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**Subjects enrolled per age group**

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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)	0
From 65 to 84 years	49
85 years and over	0

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## Subject disposition

### Recruitment

Recruitment details:

Patients were enrolled in 16 French participating centers between 19/07/2010 and 27/11/2013.

### Pre-assignment

Screening details:

Main inclusion criteria were: age >70 years; histologically proven NSCLC; unresectable stage IIIA2 or stage IIIB disease without pleural involvement or supraclavicular lymph-node invasion; PS score 0 or 1. Main exclusion criteria were: active malignancy within the past 5 years, bronchoalveolar, neuroendocrine or composite cancer histology.

### Period 1

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

### Arms

<b>Arm title</b>	Overall trial
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Vinorelbine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Oral vinorelbine 30 mg/m<sup>2</sup> for 6 weeks.

Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Weekly IV cisplatin (30 mg/m<sup>2</sup>)

Number of subjects in period 1	Overall trial
Started	49
Completed	40
Not completed	9
Consent withdrawn by subject	1
Protocol deviation	8



## Baseline characteristics

### Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	49	49	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
median	75.1		
standard deviation	± 4	-	
Gender categorical			
Units: Subjects			
Female	7	7	
Male	42	42	

## End points

### End points reporting groups

Reporting group title	Overall trial
Reporting group description: -	

### Primary: Number of patients with grade >2 clinically relevant adverse events

End point title	Number of patients with grade >2 clinically relevant adverse events <sup>[1]</sup>
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End point description:

End point type	Primary
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End point timeframe:

4 week after end of treatment

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: See attached paper

<b>End point values</b>	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: percent of patients	20			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Objective response rate (ORR)

End point title	Objective response rate (ORR)
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End point description:

Number of patients with complete response, partial responses and with stabilized disease.

End point type	Secondary
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End point timeframe:

4 weeks after the end of treatment

<b>End point values</b>	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: Percentage of patients	37			

## Statistical analyses

No statistical analyses for this end point

### Secondary: Progression-free survival (PFS).

End point title	Progression-free survival (PFS).
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End point description:

End point type	Secondary
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End point timeframe:

2 years following the last inclusion

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: Month				
median (confidence interval 95%)	15 (8.7 to 35.2)			

Attachments (see zip file)	overall survival and progression-free survival/Figure 2.docx
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## Statistical analyses

No statistical analyses for this end point

### Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
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End point description:

End point type	Secondary
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End point timeframe:

2 years after the last inclusion

<b>End point values</b>	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: month				
median (confidence interval 95%)	21.8 (16 to 21.8)			

## Statistical analyses

No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From the start of inclusions until one month after the end of treatment

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	17
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### Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 48 (20.83%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events	5		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to liver			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 1		
Injury, poisoning and procedural complications			
Radiation fibrosis			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 1		
Atrial fibrillation			

subjects affected / exposed	2 / 48 (4.17%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Vascular graft			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Catheter sepsis			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	2 / 48 (4.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Bronchial disorder			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Acute pulmonary oedema			

subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 1		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Candida sepsis			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung infection			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

<b>Non-serious adverse events</b>	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 48 (68.75%)		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 48 (16.67%)		
occurrences (all)	17		
Platelet count decreased			
subjects affected / exposed	8 / 48 (16.67%)		
occurrences (all)	13		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	16 / 48 (33.33%)		
occurrences (all)	28		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	6 / 48 (12.50%)		
occurrences (all)	10		
Dysphagia			
subjects affected / exposed	5 / 48 (10.42%)		
occurrences (all)	7		
Esophagitis			
subjects affected / exposed	11 / 48 (22.92%)		
occurrences (all)	11		
Nausea			
subjects affected / exposed	12 / 48 (25.00%)		
occurrences (all)	20		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 48 (22.92%)		
occurrences (all)	15		
Dyspnea			
subjects affected / exposed	5 / 48 (10.42%)		
occurrences (all)	10		



## 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

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/21277475>

<http://www.ncbi.nlm.nih.gov/pubmed/29858022>