Clinical trial results:
A PHASE II, OPEN-LABEL, MULTICENTER TRIAL OF CABAZITAXEL IN PATIENTS WITH RECURRENT OR METASTATIC HEAD AND NECK CANCER AFTER FAILURE OF CISPLATIN, CETUXIMAB AND TAXANES.

Summary

EudraCT number	2011-004712-32
Trial protocol	FR
Global end of trial date	14 May 2014

Results information

Result version number	v1 (current)
This version publication date	31 March 2021
First version publication date	31 March 2021

Trial information

Trial identification

Sponsor protocol code	UC-0130/1106

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01620242
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UNICANCER
Sponsor organisation address	101 RUE DE TOLBIAC, PARIS, France, 75013
Public contact	Nourredine AIT RAHMOUNE, UNICANCER, 33 0171936704, n.ait-rahmoune@unicancer.fr
Scientific contact	Nourredine AIT RAHMOUNE, UNICANCER, 33 0171936704, n.ait-rahmoune@unicancer.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:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 March 2014
Global end of trial reached?	Yes
Global end of trial date	14 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of cabazitaxel in terms of non-progression at 6 weeks for the treatment of recurrent or metastatic head and neck cancer after failure of cisplatin, cetuximab and taxanes. Non-progression will be assessed after centralized review of CT-scans.

Protection of trial subjects:

In order to ensure the protection of the rights, safety and well-being of trial subjects, this clinical trial was performed in compliance with the principles laid down in the declaration of Helsinki, good Clinical Practice and European regulation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 April 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

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)	24

From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment only in France, first inclusion on 06 April 2012 and last inclusion occured on 19 April 2013

Pre-assignment

Screening details:

PATIENTS WITH RECURRENT OR METASTATIC HEAD AND NECK CANCER AFTER FAILURE OF CISPLATIN, CETUXIMAB AND TAXANES

Period 1

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

Arms

Arm title	cabazitaxel 25 mg/m2 every 3 weeks

Arm description:

Patients will be treated with intravenous cabazitaxel 25 mg/m2 every 3 weeks (D1=D22) for 6 cycles. In absence of progression disease or unacceptable toxicity, the treatment could be continued until a maximum of 10 cycles.

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

Dosage and administration details:

Patients will be treated with intravenous cabazitaxel 25 mg/m2 every 3 weeks (D1=D22) for 6 cycles. In absence of progression disease or unacceptable toxicity, the treatment could be continued until a maximum of 10 cycles.

Number of subjects in period 1	cabazitaxel 25 mg/m2 every 3 weeks
Started	31
Completed	31

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial
Reporting group description:	
All patients included	

Reporting group values	Overall trial	Total	
Number of subjects	31	31	
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)	24	24	
From 65-84 years	7	7	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	7	7	
Male	24	24	

End points

End points reporting groups

Reporting group title	cabazitaxel 25 mg/m2 every 3 weeks

Reporting group description:

Patients will be treated with intravenous cabazitaxel 25 mg/m2 every 3 weeks (D1=D22) for 6 cycles. In absence of progression disease or unacceptable toxicity, the treatment could be continued until a maximum of 10 cycles.

Primary: Principal endpoint Non progression at 6weeks

End point title	Principal endpoint Non progression at 6weeks[1]

End point description:

Non-progression at 6 weeks will be evaluated as per RECIST criteria (v1.1)

End point type	Primary

End point timeframe:

6 weeks after treatment initiation

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: Primary endpoint: The percentage of assessable patients with non progression disease at 6 weeks will be calculated using binomial estimates and reported with its 95% confidence interval (CI).

End point values	cabazitaxel 25 mg/m2 every 3 weeks			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: percent				
arithmetic mean (confidence interval 95%)	27.6 (12.7 to 47.2)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Since inclution until 30 days after last treatment administration (no delay for related SAE)

Adverse event reporting additional description:

The extraction of non serious AEs is not compatible with the filling of the form. For all non serious AEs, the number "1" has been reported in the "Subjects affected number" section and the "Occurrences all number" section.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	12

Reporting groups

Reporting group title	all patients

Reporting group description: -

Serious adverse events	all patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 31 (58.06%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOR PAIN			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
ANEMIA			
subjects affected / exposed	2 / 31 (6.45%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
FEBRILE APLASIA			

subjects affected / exposed	4 / 31 (12.90%)			
occurrences causally related to treatment / all	4 / 4			
deaths causally related to treatment / all	0 / 0			
FEBRILE NEUTROPENIA				
subjects affected / exposed	3 / 31 (9.68%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
CHRONIC PAIN				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
DISEASE PROGRESSION				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
FACE EDEMA				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
GENERAL PHYSICAL HEALTH DETERIORATION				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
INJURY ASSOCIATED WITH DEVICE				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
DIARRHEA				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

DYSPHAGIA				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
HEMATEMESIS				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
INTESTINAL OBSTRUCTION				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
ASPIRATION PNEUMONIA				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
DYSPNEA				
subjects affected / exposed	3 / 31 (9.68%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
PNEUMOPATHY				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
STAPHYLOCOCCUS AUREUS PNEUMONIA				
subjects affected / exposed	1 / 31 (3.23%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
RENAL INSUFFICIENCY				

subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
CATHETER INFECTION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
INFECTION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
LUNG INFECTION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
SEPTIC SHOCK			
subjects affected / exposed	2 / 31 (6.45%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	1 / 1		
SEPTICEMIA			
subjects affected / exposed	1 / 31 (3.23%)		
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	all patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 31 (100.00%)		
General disorders and administration site conditions			
DOULEURS TUMORALES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		

FATIGUE/ASTHENIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
FIEVRE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
OEDEME PERIPHERIQUE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INFLAMMATION DES MUQUEUSES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
FRISSONS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
MALAISE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
CHOC SEPTIC			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
TOUX			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEUR OROPHARYNGEE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
PNEUMOPATHIE DE DEGLUTITION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DYSPNEE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DESATURATION RESPIRATOIRE			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPERSECRETION BRONCHIQUES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Cardiac disorders			
ARYTHMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
BRADYCARDIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Nervous system disorders			
CEPHALEES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
ANXIETE/DEPRESSION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
TROUBLES NEUROMOTEURS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
TROUBLES NEUROSENSORIELS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DYSGUEUSIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
VERTIGE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
LETHARGIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
SCIATIQUE			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
NEUROPATHIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
PARESTHESIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DYSESTHESIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
TREMBLEMENTS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
NEUTROPENIE FEBRILE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
ANEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION DES LEUCOCYTES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION DES PLAQUETTES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION DES NEUTROPHILES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
LYMPHOPENIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION LYMPHOCYTES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		

HYPOALBUMINEMIE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
Ear and labyrinth disorders ACOUPHENE subjects affected / exposed occurrences (all) BOURDONNEMENTS OREILLE DROITE subjects affected / exposed occurrences (all)	 1 / 31 (3.23%) 1 1 / 31 (3.23%) 1		
Eye disorders CONJONCTIVITE subjects affected / exposed occurrences (all) LARMOIEMENT AUGMENTE subjects affected / exposed occurrences (all)	 1 / 31 (3.23%) 1 1 / 31 (3.23%) 1		
Gastrointestinal disorders DIARRHEE subjects affected / exposed occurrences (all) NAUSEES subjects affected / exposed occurrences (all) VOMISSEMENTS subjects affected / exposed occurrences (all) SECHERESSE DE LA BOUCHE subjects affected / exposed occurrences (all) REFLUX GASTRO-OESOPHAGIEN subjects affected / exposed occurrences (all) HEMORROIDES subjects affected / exposed occurrences (all)	 1 / 31 (3.23%) 1 1 / 31 (3.23%) 1 1 / 31 (3.23%) 1 1 / 31 (3.23%) 1 1 / 31 (3.23%) 1 1 / 31 (3.23%) 1		

HEMORRAGIE RECTALE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS ABDOMINALES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DYSPHAGIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
CONSTIPATION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
ERYTHEME			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
PRURIT			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DEMANGEAISON			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
FOLICULITE DU VISAGE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
ONYCHOPATHIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
NECROSE DE L'ORIFICE DE LA SONDE DE GASTROSTOMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Renal and urinary disorders			
DYSURIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
COLIQUE RENALE			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HEMATURIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
POLLAKIURIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYDRONEPHROSE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
RETENTION URINAIRE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
OBSTRUCTION URETRALE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INCONTINENCE URINAIRE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INSUFFISANCE RENALE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INSUFFISANCE RENALE AIGUE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
ARTHRALGIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS DORSALES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS DES EXTREMITES			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
SPASMES MUSCULAIRES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEUR THORACIQUE MUSCULOSQUELETTIQUE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEUR AU NIVEAU DU FLANC			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
MYALGIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS OSSEUSES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS JAMBES OSSEUSES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
TRISMUS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS EPAULES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Infections and infestations			
INFECTION DES VOIES RESPIRATOIRES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
SEPTICEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
MUCITE			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
ANOREXIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DESHYDRATATION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPERGLYCEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPOKALIEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPOALBUMINEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPERKALIEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPERCALCEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 February 2012	Precision concerning the pregnancy test to be done before inclusion in the clinical trial
22 May 2012	Modification of the inclusion criteria in order to precise the cancer type included. Patient can be included after Platinium Failure (in stead of cisplatin Failure)
16 October 2012	Modification of the protocol according to the new smpc of the product

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported