



Clinical trial results:

Phase II trial of weekly Carboplatin-Paclitaxel adjuvant chemotherapy after intensity modulated extended-field chemoradiation in the treatment of locally advanced cervical cancer with para-aortic positive nodes

Summary

EudraCT number	2018-001752-35
Trial protocol	FR
Global end of trial date	20 June 2025

Results information

Result version number	v1 (current)
This version publication date	28 February 2026
First version publication date	28 February 2026

Trial information

Trial identification

Sponsor protocol code	2018-06
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04016142
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Centre Oscar Lambret
Sponsor organisation address	3 Rue Frédéric Combemale, Lille, France, 59000
Public contact	DRCI Sponsor Unit, Centre Oscar Lambret, +33 320295918, promotion@o-lambret.fr
Scientific contact	DRCI Sponsor Unit, Centre Oscar Lambret, +33 320295918, promotion@o-lambret.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	26 November 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 January 2025
Global end of trial reached?	Yes
Global end of trial date	20 June 2025
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of adjuvant chemotherapy per Carboplatin-Paclitaxel administrated in adjuvant situation after concomitant radio-chemotherapy in terms of Progression Free Survival (PFS) for patients treated for a cervical cancer locally advanced presenting positive lombo-aortic lymph nodes

Protection of trial subjects:

This study was conducted in accordance with the ethical principles of the 1964 Helsinki declaration, revised in 2013 and 2024 in Fortaleza, with the rules of Good Clinical Practice (GCP) defined by the International Conference on Harmonization (ICH-E6, 17/7/96)), and all applicable laws et regulations. The clinical trial did not begin before approval of the Ethics Committees and authorization by competent authorities concerned.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	18
From 65 to 84 years	3

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

The trial was opened in 6 french centers. 21 patients were enrolled in 2 centers from 15/06/2020 and 04/07/2023 in the part I of the study. Among these patients, 14 patients were enrolled in the part II of the study.

Pre-assignment

Screening details:

A total of 45 patients were planned in the study protocol, but only 21 patients were actually enrolled due to low recruitment.

Period 1

Period 1 title	Part 1: standard concomitant RT-CT
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Population included in part I
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Arm description:

Standard treatment

Arm type	First part of the study (standard treatment)
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intravenous use

Dosage and administration details:

Weekly cisplatin (40 mg/m²)

Number of subjects in period 1	Population included in part I
Started	21
Completed	14
Not completed	7
Patient refusal	2
Standard treatment not received in totality	1
Adverse event, non-fatal	3
Progression	1

Period 2

Period 2 title	Part 2: experimental adjuvant CT
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Population included in part II
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Arm description:

Experimental treatment

Arm type	Second part of the study (experimental treatment)
Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

80 mg/m² (+/- 5% tolerated)

Maximum dose = 160mg (corresponding to a BSA = 2.0m²)

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

Dosage and administration details:

AUC2 * (GFR + 25) mg (+/- 5% tolerated)

Maximum dose = 270 mg (corresponding to a GFR of 110ml/min)

Number of subjects in period 2	Population included in part II
Started	14
Completed	14

Baseline characteristics

Reporting groups

Reporting group title	Part 1: standard concomitant RT-CT
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Reporting group description: -

Reporting group values	Part 1: standard concomitant RT-CT	Total	
Number of subjects	21	21	
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)	18	18	
From 65-84 years	3	3	
85 years and over	0	0	
Age continuous			
Units: years			
median	52		
full range (min-max)	25 to 77	-	
Gender categorical			
Units: Subjects			
Female	21	21	
Male	0	0	

End points

End points reporting groups

Reporting group title	Population included in part I
Reporting group description:	
Standard treatment	
Reporting group title	Population included in part II
Reporting group description:	
Experimental treatment	

Primary: PFS (progression-free survival)

End point title	PFS (progression-free survival) ^[1]
End point description:	

End point type	Primary
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End point timeframe:

PFS is estimated from the date of inclusion in the part II of the trial to the date of first progression or relapse (local, lymph nodes or metastatic) or death whatever the cause. Patients alive without progression at the date of last news are censored

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 prematurely ended due to lack of recruitment. No formal statistical comparison has been performed.

End point values	Population included in part II			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: 2-years PFS rate in %				
number (confidence interval 95%)	71.4 (40.6 to 88.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: OS (overall survival)

End point title	OS (overall survival)
End point description:	

End point type	Secondary
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End point timeframe:

OS is estimated from the date of inclusion in the part II of the trial to the date of death whatever the cause. Patients alive at the date of last news are censored

End point values	Population included in part II			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: 2-years OS rate in %				
number (confidence interval 95%)	91.7 (53.9 to 98.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: MFS (metastatic-free survival)

End point title	MFS (metastatic-free survival)
End point description:	
End point type	Secondary
End point timeframe:	
MFS is estimated from the date of inclusion in the part II until the date of first metastatic progression or death whatever the cause. Patients alive without metastatic progression at the date of last news are censored at this date	

End point values	Population included in part II			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: 2-years MFS rate in %				
number (confidence interval 95%)	78.6 (47.2 to 92.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Feasibility

End point title	Feasibility
End point description:	
The number of cycles will be recorded	
End point type	Secondary

End point timeframe:

During the experimental treatment

End point values	Population included in part II			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: Number of chemotherapy cycles started	14			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

For the 2nd part of the study, all AE are reported up to 30 days after the end of adjuvant chemotherapy, until progression if any. Then, only AE possibly related to chemotherapy or radiation therapy are collected, up to 5 years after end of RT

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	Adverse events
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Reporting group description: -

Serious adverse events	Adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 14 (7.14%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Immune system disorders			
Anaphylactic reaction	Additional description: Anaphylactic reaction		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)		
Vascular disorders			
Hot flush	Additional description: Hot flush		
subjects affected / exposed	4 / 14 (28.57%)		
occurrences (all)	7		
Lymphoedema	Additional description: Lymphoedema		
subjects affected / exposed	4 / 14 (28.57%)		
occurrences (all)	5		
Surgical and medical procedures			

Glaucoma surgery subjects affected / exposed occurrences (all)	Additional description: Glaucoma surgery		
	1 / 14 (7.14%) 1		
General disorders and administration site conditions			
	Additional description: Asthenia		
	11 / 14 (78.57%) 25		
	Additional description: Mucosal inflammation		
	2 / 14 (14.29%) 2		
	Additional description: Oedema peripheral		
	2 / 14 (14.29%) 2		
	Additional description: Pyrexia		
	2 / 14 (14.29%) 3		
Reproductive system and breast disorders			
	Additional description: Breast haematoma		
	1 / 14 (7.14%) 1		
	Additional description: Dyspareunia		
	3 / 14 (21.43%) 3		
	Additional description: Intermenstrual bleeding		
	2 / 14 (14.29%) 2		
	Additional description: Menopausal symptoms		
	1 / 14 (7.14%) 1		
	Additional description: Pelvic pain		
	4 / 14 (28.57%) 4		
	Additional description: Rectocele		
	1 / 14 (7.14%) 1		
	Additional description: Uterine fibrosis		

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	4		
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Vulvovaginal dryness	Additional description: Vulvovaginal dryness		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Vulvovaginal swelling	Additional description: Vulvovaginal swelling		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough	Additional description: Cough		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	4		
Psychiatric disorders			
Sleep disorder	Additional description: Sleep disorder		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Investigations			
Blood folate decreased	Additional description: Blood folate decreased		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Eosinophil count increased	Additional description: Eosinophil count increased		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Transaminases increased	Additional description: Transaminases increased		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			

Compression fracture subjects affected / exposed occurrences (all)	Additional description: Compression fracture	
	1 / 14 (7.14%)	
	1	
	Additional description: Contusion	
	1 / 14 (7.14%)	
Contusion subjects affected / exposed occurrences (all)	1	
	Additional description: Face injury	
	1 / 14 (7.14%)	
	1	
	Additional description: Fracture	
Fracture subjects affected / exposed occurrences (all)	1 / 14 (7.14%)	
	1	
	Additional description: Pelvic fibrosis	
	1 / 14 (7.14%)	
	1	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	Additional description: Dizziness	
	3 / 14 (21.43%)	
	3	
	Additional description: Dysgeusia	
	2 / 14 (14.29%)	
	2	
	Additional description: Headache	
	4 / 14 (28.57%)	
	4	
	Additional description: Hypoaesthesia	
	1 / 14 (7.14%)	
	1	
	Additional description: Neuropathy peripheral	
	11 / 14 (78.57%)	
	25	
	Additional description: Paraesthesia	
	5 / 14 (35.71%)	
	5	
	Additional description: Sciatica	

subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Syncope	Additional description: Syncope		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Uraemic neuropathy	Additional description: Uraemic neuropathy		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	13 / 14 (92.86%)		
occurrences (all)	37		
Hyperleukocytosis	Additional description: Hyperleukocytosis		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	12 / 14 (85.71%)		
occurrences (all)	24		
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	7 / 14 (50.00%)		
occurrences (all)	16		
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	8 / 14 (57.14%)		
occurrences (all)	11		
Ear and labyrinth disorders			
Deafness	Additional description: Deafness		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Tinnitus	Additional description: Tinnitus		

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Eye disorders			
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Visual field defect	Additional description: Visual field defect		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Burn oesophageal	Additional description: Burn oesophageal		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Constipation	Additional description: Constipation		
subjects affected / exposed	5 / 14 (35.71%)		
occurrences (all)	6		
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	10 / 14 (71.43%)		
occurrences (all)	16		
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	5 / 14 (35.71%)		
occurrences (all)	11		
Flatulence	Additional description: Flatulence		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	2		
Haemorrhoids	Additional description: Haemorrhoids		

subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Nausea	Additional description: Nausea		
subjects affected / exposed	7 / 14 (50.00%)		
occurrences (all)	22		
Odynophagia	Additional description: Odynophagia		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Vomiting	Additional description: Vomiting		
subjects affected / exposed	5 / 14 (35.71%)		
occurrences (all)	11		
Proctitis	Additional description: Proctitis		
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	3		
Toothache	Additional description: Toothache		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Alopecia	Additional description: Alopecia		
subjects affected / exposed	7 / 14 (50.00%)		
occurrences (all)	8		
Dry skin	Additional description: Dry skin		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Telangiectasia	Additional description: Telangiectasia		
subjects affected / exposed	6 / 14 (42.86%)		
occurrences (all)	6		
Renal and urinary disorders			
Dysuria	Additional description: Dysuria		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Incontinence	Additional description: Incontinence		

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	2		
Nocturia	Additional description: Nocturia		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	4		
Back pain	Additional description: Back pain		
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	4		
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Myalgia	Additional description: Myalgia		
subjects affected / exposed	6 / 14 (42.86%)		
occurrences (all)	6		
Neck pain	Additional description: Neck pain		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Infections and infestations			
Covid-19	Additional description: Covid-19		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Cystitis	Additional description: Cystitis		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Gastroenteritis	Additional description: Gastroenteritis		

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Genital infection	Additional description: Genital infection		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Cell death	Additional description: Cell death		
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	3		
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Iron deficiency	Additional description: Iron deficiency		
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 March 2020	<p>Protocol, and synopsis:</p> <ul style="list-style-type: none">•Modification of the delay between the baseline assessments and inclusion in Part 1, going from 7 days to 28 days. The biological assessment must be carried out within 7 days before the start of treatment.•Modification of gynecological monitoring: it will not be requested at each visit during the treatment cycles: these examinations must be carried out at baseline, before the start of Part 2 and at the end of the study (at the end of treatment) and when necessary•Pregnancy tests: this test remains necessary at baseline for validation of inclusion, it will then no longer be carried out automatically and mandatory at other times of the study, because the sterilizing effect of radiotherapy is recognized.•Modification of an inclusion criterion for Part 2: "Patients who received chemotherapy + concomitant boost on macroscopic lymph nodes" modified by "Patients who received chemotherapy that can be associated with a concomitant boost on macroscopic lymph nodes." » Because not all patients will receive this boost since it depends on the presence or not of lymph nodes visible macroscopically on the PET scan.•Concomitant treatments: it is added that treatment with EPO is not recommended.•Modification of an inclusion criterion for Part 2: "Patients who received chemotherapy + concomitant boost on macroscopic lymph nodes" is replaced by "Patients who received chemotherapy that can be associated with a concomitant boost on macroscopic lymph nodes." », because not all patients will receive this boost since it depends on the presence or not of lymph nodes visible macroscopically on the PET scan•Concomitant treatments: it is added that treatment with EPO is not recommended. <p>Trial site list:</p> <ul style="list-style-type: none">•Declaration of 3 new investigators for site n°1 (Centre Oscar Lambret, Lille) <p>Informed consent form:</p> <ul style="list-style-type: none">•Conduct of the study: modification of the duration of the assessment planned for inclusion in Part 1, going from 7 days
27 March 2020	<ul style="list-style-type: none">• Temporary halt of inclusions on 27-MAR-2020 due to the health situation linked to Covid-19• Restart of inclusions on 26-MAY-2020 in the conditions prior to the transitional measures linked to Covid-19
23 February 2021	<p>Trial site list:</p> <ul style="list-style-type: none">• Declaration of a new investigator for site n°1 (Centre Oscar Lambret, Lille)• Addition of a 6th trial site: Lens Hospital Center, represented by Dr. FOURQUET as principal investigator

14 June 2021	<p>Protocol, and synopsis:</p> <ul style="list-style-type: none"> • Addition of recommendations linked to the anti-COVID vaccine strategy <p>Trial site lists:</p> <ul style="list-style-type: none"> • Declaration of a new investigator for site n°2 (Centre Léonard de Vinci) <p>SmPC PACLITAXEL 6mg/ml:</p> <ul style="list-style-type: none"> • Update of the document (version of 14-JUNE-2021), with the description of a new adverse event of undetermined frequency: palmoplantar erythrodysesthesia which may persist beyond 6 months after stopping treatment. This modification has an impact on the expected/unexpected nature of the SARs and the conduct of the study; it is therefore considered substantial but does not require an update of the protocol (this already specifies the action to be taken in the event of peripheral neuropathies) nor the informed consent form given to patients (which already includes the list of frequent and very frequent adverse effects)
21 November 2022	<p>Protocol, and synopsis:</p> <ul style="list-style-type: none"> • Extension of the recruitment period by 6 months and update of the study schedule. The duration of exposure to the investigational drug is not extended, the definition of the end of the trial and the monitoring conditions are unchanged. At the end of this extension, the study will be definitively closed to recruitment. <p>Protocol:</p> <ul style="list-style-type: none"> • Compliance of the protocol with the SPC of paclitaxel dated 04-MAR-2021: addition of new contraindicated combinations with paclitaxel <p>Informed consent form:</p> <ul style="list-style-type: none"> • Information on the recruitment period is deleted because it is calculated on the total number of patients initially expected, however, the objective is now to reach 50% of inclusions (23 patients) by 30-JUNE-2023. • Information on the delay necessary to obtain results is also removed, for the same reasons as above. • Addition of a safety instruction related to the contraceptive method. • Addition of a paragraph to allow the reuse of data for other research (retrospective cohorts, etc.) • Update of the CNIL URL to allow patients to send a complaint to the CNIL; the postal address is also specified <p>SmPC PACLITAXEL 6mg/ml</p> <ul style="list-style-type: none"> • Update of the document (version of 04-MAR-2021). Some of the modifications have an impact on the list of concomitant treatments to avoid • Addition of contraindicated combinations of paclitaxel with St. John's wort, live attenuated vaccines; • Addition of associations not recommended with new enzyme inducers not described in the previous version of the SPC) and fosphenytoin).
20 June 2025	<p>Protocol and synopsis:</p> <ul style="list-style-type: none"> • The follow-up of patients is interrupted on 31-JAN-2025 (=LPLV) • Addition of a paragraph regarding the modification of the end of the trial, and its justification • Compliance of the duration of follow-up with the end of the study <p>New document:</p> <ul style="list-style-type: none"> • Introduction of a new letter to inform patients of the end of the study <p>Insurance:</p> <ul style="list-style-type: none"> • The insurance certificate is updated following the new definition of end of study <p>Note:</p> <p>This substantial amendment was released for information to regulatory authorities since the trial had already been completed, and because the platform for submitting amendments to the french Ethics Committee (SI RIPH 2G) does not allow to submit amendment after the end of the study. However, the Ethics Committee received and examined the documents outside the usual procedure and made a comment on the information letter. All modifications requested by the Ethics Committee regarding the information letter have been made.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
27 March 2020	Temporary discontinuation (Covid), then permanent discontinuation because recruitment targets were very difficult to achieve with only two active sites (four of the six sites opened did not include any patients).	26 May 2020

Notes:

Limitations and caveats

None reported