Clinical trial results:
Phase II Randomized Study Measuring the Interest of Pursuing or Not the chemotherapy for Non-progressive Patients With Metastatic Esophageal Squamous-cell Cancer After 6 Weeks of LV5FU2-paclitaxel Given After a 1st Line Fluoropyrimidin/Pt Salt chemotherapy

Summary

EudraCT number	2017-003660-13
Trial protocol	FR
Global end of trial date	16 June 2023

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	E-DIS-2-1705

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03301454
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Centre Oscar Lambret
Sponsor organisation address	3 rue Frédéric Combemale – BP307 , LILLE, France, 59020
Public contact	Sponsor unit, Centre Oscar Lambret, +33 320295918, promotion@o-lambret.fr
Scientific contact	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	16 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 June 2023
Global end of trial reached?	Yes
Global end of trial date	16 June 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Estimate the overall survival for patients suffering from non-progressive Esophageal cancer at and after 6 weeks of treatment until progression

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 August 2018
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: 9
Worldwide total number of subjects	9
EEA total number of subjects	9

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)	3
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Of the 15 patients recruited in the study, 9 were randomized between 01/10/2018 and 27/01/2022
The study ended prematurely due to very low accrual.

Pre-assignment

Screening details:

Of the 15 patients included, 9 were randomised between 01/10/2018 and 27/01/2022

Period 1

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

Blinding implementation details:

Patients included in the randomised trial after 6 cycles of LV5FU2-paclitaxel (N=9)

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A - Continuation of chemotherapy

Arm description:

Continuation of chemotherapy until progression + improved supportive care
3 cycles of LV5FU2 (Bolus 5-FU 400mg/m²
- continuous 5-FU over 46h: 3000 mg/m², calcium folinate 400 mg/m² or calcium levofolinate 200 mg/m²)
- paclitaxel (100 mg/m² Day 1)

Arm type	Experimental
Investigational medicinal product name	LV5FU2 + paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for injection
Routes of administration	Injection

Dosage and administration details:

Continuation of chemotherapy until progression + improved supportive care
3 cycles of LV5FU2 (Bolus 5-FU 400mg/m²
- continuous 5-FU over 46h: 3000 mg/m², calcium folinate 400 mg/m² or calcium levofolinate 200 mg/m²)
- paclitaxel (100 mg/m² Day 1)

Arm title	Arm B - Treatment discontinuation

Arm description:

Interruption of chemotherapy + improved supportive care.

Arm type	Supportive care

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Arm A - Continuation of chemotherapy	Arm B - Treatment discontinuation
Started	4	5
Completed	4	5

Baseline characteristics

Reporting groups

Reporting group title	Arm A - Continuation of chemotherapy

Reporting group description:

Continuation of chemotherapy until progression + improved supportive care
3 cycles of LV5FU2 (Bolus 5-FU 400mg/m²
- continuous 5-FU over 46h: 3000 mg/m², calcium folinate 400 mg/m² or calcium levofolinate 200 mg/m²)
- paclitaxel (100 mg/m² Day 1)

Reporting group title	Arm B - Treatment discontinuation

Reporting group description:

Interruption of chemotherapy + improved supportive care.

Reporting group values	Arm A - Continuation of chemotherapy	Arm B - Treatment discontinuation	Total
Number of subjects	4	5	9
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	1	3
From 65-84 years	2	4	6
85 years and over	0	0	0
Age continuous Units: years			
median	66.5	71	
full range (min-max)	60 to 81	56 to 77	-
Gender categorical Units: Subjects			
Female	0	3	3
Male	4	2	6
Histology			
Squamous cell carcinoma of the esophagus			
Units: Subjects			
Squamous cell carcinoma of the esophagus	4	5	9
Type of metastases			
Type of metastases			
Units: Subjects			
Synchronous	2	2	4
Metachronous	2	2	4
Missing data	0	1	1

End points

End points reporting groups

Reporting group title	Arm A - Continuation of chemotherapy

Reporting group description:

Continuation of chemotherapy until progression + improved supportive care
3 cycles of LV5FU2 (Bolus 5-FU 400mg/m²
- continuous 5-FU over 46h: 3000 mg/m², calcium folinate 400 mg/m² or calcium levofolinate 200 mg/m²)
- paclitaxel (100 mg/m² Day 1)

Reporting group title	Arm B - Treatment discontinuation

Reporting group description:

Interruption of chemotherapy + improved supportive care.

Primary: Overall Survival (not evaluated)

End point title	Overall Survival (not evaluated)[1]

End point description:

The overall survival was not estimated because only 9 patients were recruited in the randomized trial

End point type	Primary

End point timeframe:

The overall survival was not estimated because only 9 patients were recruited in the randomized trial

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: No statistical analyses for this end point. The overall survival was not estimated because only 9 patients were recruited in the randomized trial

End point values	Arm A - Continuation of chemotherapy	Arm B - Treatment discontinuation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	5		
Units: Not applicable	4	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

A total of 5 events were reported to the pharmaco-vigilance unit including 5 Serious Adverse Events

Adverse event reporting additional description:

- 2 SAE in initial phase of treatment (chest pain, cardiac decompensation)
- 2 SAE after randomisation
  - -1 in arm A (left inguino-scrotal hernia)
  - -1 in arm B (hypokalemia)
- 1 case of special situation (administration error with associated adverse event)

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20

Reporting groups

Reporting group title	Arm A - Continuation of chemotherapy

Reporting group description:

Arm A - Continuation of chemotherapy

Reporting group title	Arm B - Treatment discontinuation

Reporting group description:

Arm B - Treatment discontinuation

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Only SAEs were recorded because the study was terminated prematurely.

Serious adverse events	Arm A - Continuation of chemotherapy	Arm B - Treatment discontinuation	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	
number of deaths (all causes)	3	2	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Cardiac disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Inguinal hernia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Calcium levofolinate overdose	Additional description: CALCIUM LEVOFOLINATE OVERDOSE		
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Arm A - Continuation of chemotherapy	Arm B - Treatment discontinuation	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 October 2018	- Updated List of centres, -Calcium levolinate dose correction, -modification of study treatment discontinuation criteria, -Updated Subject information sheet, informed consent form -Compliance GDPR
31 October 2019	- Inclusion criteria modification : testing for DPD deficiency - cardiac monitoring added - Calcium levolinate dose correction, - update study schedule
02 October 2020	- Updated List of centres - Updated study scheme - clarification of adverse event not to be reported to PV
20 April 2021	- Updated List of centres, - Updated study scheme - Updated Paclitaxel SPC with impact on protocol
29 July 2021	- Updated List of centres
07 January 2022	- Updated List of centres
09 March 2022	- Updated Fluorouracile SPC with impact on protocol

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
16 June 2023	The study was stopped prematurely due to a lack of recruitment. Indeed, after more than 3 years of recruitment, only 15 patients had been included, and 9 were randomized. As a result, this study will unfortunately not be able to be scientifically exploited.	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was stopped prematurely due to a lack of recruitment.

Notes: