Clinical trial results:
Evaluation de l'efficacité et de la tolérance du Lanreotide LP 90 mg versus placebo dans la diminution de la lyphorrhée post curage axillaire dans les cancers du sein.

Summary

EudraCT number	2007-003576-19
Trial protocol	FR
Global end of trial date	23 June 2011

Results information

Result version number	v1 (current)
This version publication date	01 June 2021
First version publication date	01 June 2021
Summary attachment (see zip file)	2007-003576-19_results (Lanreotide_PUBLICATION.pdf)

Trial information

Trial identification

Sponsor protocol code	I07015

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00630695
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 Yves AUBARD, CHU de lImoges, 33 550552109, yves.aubard@unilim.fr
Scientific contact	Pr Yves AUBARD, CHU de lImoges, 33 550552109, yves.aubard@unilim.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	23 June 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 June 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of Lanreotide Autogel 90 mg PR to prevent lymphorrhea after axillary dissection in breast cancer.

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. The patients were included after transparent information on the interests and risks associated with the research. Consent was systematically obtained after information, answers to patients' questions and a period of reflection.

In addition to the scheduled visits, patients were invited to contact the service before these visits, in case of problems, regardless of the date, especially in the event of the appearance of painful axillary effusion or the appearance of side effects of treatment (diarrhea, abdominal pain ...).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2008
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: 147
Worldwide total number of subjects	147
EEA total number of subjects	147

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)	133
From 65 to 84 years	12
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

All patients were recruited at CHU limoges Hospital between april 2008 and december 2010.

Pre-assignment

Screening details:

Eligibility criteria: the patients included were over-18- year-old women with breast cancer who had to undergo axillary lymph node dissection (AD) either alone or with either lumpectomy or mastectomy. Exclusion criteria were diabetes mellitus with insulinotherapy, cyclosporin treatment, kidney failure and pregnancy. T

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Treatment group received one deep subcutaneous (sc) 0.3 ml injection of Lanreotide Autogel 90 mg PR (Somatuline)) and the control group received one sc injection of 0.3 ml saline preparation using the same protocol. Because lanreotide and placebo look different, only the nurse who gave the injection knew what was injected. This nurse was excluded from both patient follow up and data measurements.

Arms

Are arms mutually exclusive?	Yes
Arm title	LANREOTIDE

Arm description:

In this expirimental group, patients received one deep subcutaneous (sc) 0.3 ml injection of Lanreotide Autogel 90 mg PR (Somatuline)

Arm type	Experimental
Investigational medicinal product name	LANREOTIDE
Investigational medicinal product code	
Other name	Somatoline
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.3 ml injection of Lanreotide Autogel 90 mg PR

Arm title	Placebo

Arm description:

Placebo group received one sc injection of 0.3 ml saline preparation

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

One sc injection of 0.3 ml saline preparation

Number of subjects in period 1	LANREOTIDE	Placebo
Started	73	74
Completed	72	73
Not completed	1	1
Protocol deviation	1	1

Baseline characteristics

Reporting groups	
Reporting group title	LANREOTIDE
Reporting group description:	
In this expirimental group, patients received one deep subcutaneous (sc) 0.3 ml injection of Lanreotide Autogel 90 mg PR (Somatuline)	
Reporting group title	Placebo
Reporting group description:	
Placebo group received one sc injection of 0.3 ml saline preparation	

Reporting group values	LANREOTIDE	Placebo	Total
Number of subjects	73	74	147
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)	68	65	133
From 65-84 years	4	8	12
85 years and over	1	1	2
Gender categorical Units: Subjects			
Female	73	74	147
Male	0	0	0

End points

End points reporting groups

Reporting group title	LANREOTIDE
Reporting group description:	
In this expirimental group, patients received one deep subcutaneous (sc) 0.3 ml injection of Lanreotide Autogel 90 mg PR (Somatuline)	
Reporting group title	Placebo
Reporting group description:	
Placebo group received one sc injection of 0.3 ml saline preparation	

Primary: Postoperative lymphorrhea volume

End point title	Postoperative lymphorrhea volume
End point description:	
End point type	Primary
End point timeframe:	
At day 4 postoperative	

End point values	LANREOTIDE	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	72	73		
Units: Volume				
arithmetic mean (standard deviation)	330 (± 182)	383 (± 230)		

Statistical analyses

Statistical analysis title	Mann Whitney test
Comparison groups	LANREOTIDE v Placebo
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18 [1]
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - Not statistically significant (p= 0.18).

Secondary: Postoperative reduction of lymphorrhea volume

End point title	Postoperative reduction of lymphorrhea volume
End point description:	
End point type	Secondary

End point timeframe: At 15 day postoperative

End point values	LANREOTIDE	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	70	71		
Units: Volume(ml)				
number (not applicable)	317.5	407		

Statistical analyses

Statistical analysis title	Mann Whitney test.
Comparison groups	LANREOTIDE v Placebo
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26
Method	Wilcoxon (Mann-Whitney)

Secondary: Postoperative reduction of lymphorrhea volume
End point title: Postoperative reduction of lymphorrhea volume
End point description:
End point type: Secondary
End point timeframe: At 30 day posteoperative

End point values	LANREOTIDE	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68	69		
Units: Volume (ml)				
number (not applicable)	327.5	407		

Statistical analyses

Statistical analysis title	Mann Whitney test.
Comparison groups	LANREOTIDE v Placebo

Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26
Method	Wilcoxon (Mann-Whitney)

Secondary: Postoperative reduction of lymphorrhea volume

End point title	Postoperative reduction of lymphorrhea volume

End point description:

End point type	Secondary

End point timeframe:

At 180 days posteoperative

End point values	LANREOTIDE	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	63		
Units: Volume (ml)				
number (not applicable)	317.5	403		

Statistical analyses

Statistical analysis title	Mann Whitney test.
Comparison groups	LANREOTIDE v Placebo
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were assessed fron inclusion til 30 days after treatment injection.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.0

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 147 (12.24%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	2		
Injury, poisoning and procedural complications			
Phlebitis			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Subclavian vein thrombosis			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemorrhage			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Epistaxis			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Fibrillation ventricular			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Exeresis			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematoma drainage			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess breast drainage			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	2 / 147 (1.36%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Depressive symptom			

subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastrointestinal obstruction			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
ACUTE CHOLECYSTITIS			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
GASTRO-DUODENAL ULCER			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Distress respiratory			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Radius fracture			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Breast infection			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis of colon			

subjects affected / exposed	1 / 147 (0.68%)		
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	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 147 (18.37%)		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	11 / 147 (7.48%)		
occurrences (all)	11		
Vomiting			
subjects affected / exposed	7 / 147 (4.76%)		
occurrences (all)	7		
Nausea			
subjects affected / exposed	9 / 147 (6.12%)		
occurrences (all)	9		

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

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/2270375