Clinical trial results:
Evaluation of the impact of a Sandostatin injection before axillary node dissection on lymphorrhea in patients operated for breast cancer

Summary

EudraCT number	2015-004337-27
Trial protocol	FR
Global end of trial date	25 May 2017

Results information

Result version number	v1 (current)
This version publication date	23 March 2022
First version publication date	23 March 2022

Trial information

Trial identification

Sponsor protocol code	ICO-A-2015-03

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03791736
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Institut de Cancérologie de l'Ouest
Sponsor organisation address	15 rue André Boquel, ANGERS, France, 49055
Public contact	Marine TIGREAT, Institut de Cancérologie de l'Ouest, 0033 240679878, marine.tigreat@ico.unicancer.fr
Scientific contact	Marine TIGREAT, Institut de Cancérologie de l'Ouest, 0033 240679878, marine.tigreat@ico.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	20 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 May 2017
Global end of trial reached?	Yes
Global end of trial date	25 May 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective is to reduce by 50% the incidence of lymphorrhea (change from 30% to 15%) following axillary node dissection in patients operated for breast cancer (without mastectomy) pre-treated with an injection of Sandostatine®.

Protection of trial subjects:

In order to ensure the protection of the rights and the safety of trial subjects, this clinical trial was performed in compliance with the principles laid down in the declaration oh Helsinki, good clinical pratice and European regulation

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 July 2016
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: 4
Worldwide total number of subjects	4
EEA total number of subjects	4

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)	1
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inclusion must be made at least 3 days before the planned date of surgery (elective axillary dissection).

After checking the inclusion and non-inclusion criteria and signing the consent, inclusion will be done directly online via the e-CRF.

The patient number will be incremented automatically.

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	Sandostatine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Octréotide acétate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection of sandostatin 30 mg 3 days before surgery

Number of subjects in period 1	Sandostatine
Started	4
Completed	4

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	4	4	
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)	1	1	
From 65-84 years	3	3	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	4	4	
Male	0	0	

End points

End points reporting groups

Reporting group title	Sandostatine

Reporting group description: -

Primary: Number of patients who had at least one lymphocele requiring an evacuation puncture

End point title	Number of patients who had at least one lymphocele requiring an evacuation puncture[1]

End point description:

End point type	Primary

End point timeframe:

2 months after surgery

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 stopped prematurely after the inclusion of 4 patients. No analysis was performed

End point values	Sandostatine			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Patient	4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events have been reported from inclusion until 2 months after product administration

Assessment type	Systematic

Dictionary used

Dictionary name	CTC AE
Dictionary version	4

Reporting groups

Reporting group title	Axillary dissection

Reporting group description: -

Serious adverse events	Axillary dissection		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Axillary dissection		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)		

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: I confirm that there was not adverses events

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 February 2017	Update of the list of investigators

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The trial ended prematurely after the inclusion of 4 patients.
No statistical analyse could be possible and only a description of population's characteristics has been realized

Notes: