



## 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:

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**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:

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**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 of Helsinki, good clinical practice 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:

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**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:

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**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<br>(gestational age < 37 wks) | 0             | 0     |  |
| Newborns (0-27 days)                                  | 0             | 0     |  |
| Infants and toddlers (28 days-23<br>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 <sup>[1]</sup> |
|-----------------|--|

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<sup>[1]</sup>

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:

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### 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: