



Clinical trial results:

A PHASE II, SINGLE-CENTRE, PROSPECTIVE EXPLORATORY TRIAL TO ASSESS THE EFFICACY OF LANREOTIDE AUTOGEL 120 MG IN THE SYMPTOMATIC TREATMENT OF ACUTE RADIATION INDUCED DIARRHEA

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2016-001790-33 |
| Trial protocol | BE |
| Global end of trial date | 27 July 2018 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 11 August 2021 |
| First version publication date | 11 August 2021 |
| Summary attachment (see zip file) | Statement of discontinuation (2016-001790-33.docx) |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | AGO/2016/005 |
|-----------------------|--------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Ghent University Hospital |
| Sponsor organisation address | Corneel Heymanslaan 10, Ghent, Belgium, 9000 |
| Public contact | Hiruz CTU, University Hospital Ghent, 32 93320504, hiruz.ctu@uzgent.be |
| Scientific contact | Hiruz CTU, University Hospital Ghent, 32 93320504, hiruz.ctu@uzgent.be |

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 | 27 July 2018 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 27 July 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the response (complete and/or partial) of lanreotide autogel 120 mg as add-on to loperamide 16 mg on stool frequency and loperamide intake in patients with radiation induced diarrhea not enough responding to loperamide 16 mg monotherapy compared to baseline.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 01 June 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 | Belgium: 99999 |
| Worldwide total number of subjects | 99999 |
| EEA total number of subjects | 99999 |

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) | 99999 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants.

Pre-assignment

Screening details:

Inclusion criteria:

- Male or female with radiation induced diarrhoea requiring daily loperamide intake (≥ 16 mg) for at least 3 consecutive days.
- Administration of lanreotide 120mg at least 7 days before ending radiotherapy.
- ≤ 3 stools per 24 h before radiotherapy
- > 3 stools per 24 h in the screening period.
- ≥ 18 years
- mentally fit

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Blinding implementation details:

N/A

Arms

| | |
|------------------------------|----|
| Are arms mutually exclusive? | No |
|------------------------------|----|

| | |
|------------------|--------------|
| Arm title | Baseline arm |
|------------------|--------------|

Arm description:

Baseline data for the study, as the study only has 1 arm

| | |
|----------|--------------|
| Arm type | Baseline arm |
|----------|--------------|

No investigational medicinal product assigned in this arm

| | |
|------------------|---------------|
| Arm title | Treatment arm |
|------------------|---------------|

Arm description: -

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Somatuline Autogel Injectable 60 / 90 / 120 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

-Solution for injection in pre-filled syringe

-120 mg milligram(s)

-Maximum duration of treatment of a subject according to the protocol:

1 injection at inclusion

| Number of subjects in period 1 | Baseline arm | Treatment arm |
|---------------------------------------|--------------|---------------|
| Started | 99999 | 99999 |
| Completed | 99999 | 99999 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|---------------|
| Reporting group title | Overall Trial |
| Reporting group description: - | |

| Reporting group values | Overall Trial | Total | |
|---|---------------|-------|--|
| Number of subjects | 99999 | 99999 | |
| Age categorical | | | |
| 99999 is "Not applicable" value or 0 participants. | | | |
| 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) | 99999 | 99999 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| 99999 is "Not applicable" value or 0 participants. | | | |
| Units: Subjects | | | |
| Female | 99999 | 99999 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|--|---------------|
| Reporting group title | Baseline arm |
| Reporting group description: | |
| Baseline data for the study, as the study only has 1 arm | |
| Reporting group title | Treatment arm |
| Reporting group description: - | |

Primary: Complete response: loperamide-intake reduction of 75% or more and ≤ 3 stools per 24 hours.

| | |
|------------------------|--|
| End point title | Complete response: loperamide-intake reduction of 75% or more and ≤ 3 stools per 24 hours. ^[1] |
| End point description: | |

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Response is assessed at day 14 (d12-14), 28 (d26-28) and 42 (d40-42) compared to baseline (d-3 to d-1).

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 analysis available.

| End point values | Baseline arm | Treatment arm | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 99999 ^[2] | 99999 ^[3] | | |
| Units: complete response | | | | |
| number (not applicable) | 0 | 0 | | |

Notes:

[2] - Baseline data for the study, as the study only has 1 arm.

[3] - No patients were enrolled in the study.

Statistical analyses

No statistical analyses for this end point

Primary: Partial response: loperamide-intake reduction of 50% up to 75% and ≤ 3 stools per 24 hours

| | |
|-----------------|--|
| End point title | Partial response: loperamide-intake reduction of 50% up to 75% and ≤ 3 stools per 24 hours ^[4] |
|-----------------|--|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Response is assessed at day 14 (d12-14), 28 (d26-28) and 42 (d40-42) compared to baseline (d-3 to d-1).

Notes:

[4] - 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 analysis available.

| End point values | Baseline arm | Treatment arm | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 99999 ^[5] | 99999 ^[6] | | |
| Units: partial response | | | | |
| number (not applicable) | 0 | 0 | | |

Notes:

[5] - Baseline data for the study, as the study only has 1 arm.

[6] - No patients were enrolled in the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of all adverse events

| | |
|--|---------------------------------|
| End point title | Incidence of all adverse events |
| End point description: | |
| End point type | Secondary |
| End point timeframe: throughout the trial | |

| End point values | Baseline arm | Treatment arm | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 99999 ^[7] | 99999 ^[8] | | |
| Units: adverse events | | | | |
| number (not applicable) | 0 | 0 | | |

Notes:

[7] - Baseline data for the study, as the study only has 1 arm.

[8] - No patients were enrolled in this study.

Statistical analyses

No statistical analyses for this end point

Secondary: Assessing any difference in primary or secondary (point 1 to 3) effect between patients receiving concomitant chemotherapy or not receiving chemotherapy.

| | |
|--|---|
| End point title | Assessing any difference in primary or secondary (point 1 to 3) effect between patients receiving concomitant chemotherapy or not receiving chemotherapy. |
| End point description: | |
| End point type | Secondary |
| End point timeframe: Throughout the trial | |

| End point values | Baseline arm | Treatment arm | | |
|---|----------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 99999 ^[9] | 99999 ^[10] | | |
| Units: difference in primary/secondary effect | | | | |
| number (not applicable) | 0 | 0 | | |

Notes:

[9] - Baseline data for the study, as the study only has 1 arm.

[10] - No patients were enrolled in this study.

Statistical analyses

No statistical analyses for this end point

Secondary: Timing of normalization of stools (no loperamide intake and <3/stools per 24 hours)

| | |
|-----------------|---|
| End point title | Timing of normalization of stools (no loperamide intake and <3/stools per 24 hours) |
|-----------------|---|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

After ending of treatment if no complete response was reached during treatment

| End point values | Baseline arm | Treatment arm | | |
|-----------------------------|-----------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 99999 ^[11] | 99999 ^[12] | | |
| Units: timing | | | | |
| number (not applicable) | 0 | 0 | | |

Notes:

[11] - Baseline data for the study, as the study only has 1 arm.

[12] - No patients were enrolled in this study.

Statistical analyses

No statistical analyses for this end point

Secondary: Timing of first partial and complete response

| | |
|-----------------|---|
| End point title | Timing of first partial and complete response |
|-----------------|---|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Response is assessed at day 14 (d12-14), 28 (d26-28) and 42 (d40-42) compared to baseline (d-3 to d-1).

| End point values | Baseline arm | Treatment arm | | |
|-----------------------------|-----------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 99999 ^[13] | 99999 ^[14] | | |
| Units: time | | | | |
| number (not applicable) | 0 | 0 | | |

Notes:

[13] - Baseline data for the study, as the study only has 1 arm.

[14] - No patients were enrolled in this study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in QOL (assess using EQ-5D-5L, EORTC QLQ-C30)

| | |
|-----------------|--|
| End point title | Change in QOL (assess using EQ-5D-5L, EORTC QLQ-C30) |
|-----------------|--|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 14/28 compared to baseline

| End point values | Baseline arm | Treatment arm | | |
|-----------------------------|-----------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 99999 ^[15] | 99999 ^[16] | | |
| Units: QOL | | | | |
| number (not applicable) | 0 | 0 | | |

Notes:

[15] - Baseline data for the study, as the study only has 1 arm.

[16] - No patients were enrolled in this study

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Overall study

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|----|
| Dictionary version | 24 |
|--------------------|----|

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

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: No non-serious adverse events were recorded.

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

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

| |
|---|
| No patients were included due to the fact that there has been a sharp decrease in radiotherapy-related bowel toxicity because of improving radiotherapy techniques. |
|---|

Notes: