



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) ompared 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: