



Clinical trial results:

A Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability and Preliminary Efficacy of NLX-112 versus Placebo in Levodopa-induced Dyskinesia in Parkinson's Disease

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2020-006053-22 |
| Trial protocol | SE |
| Global end of trial date | 18 January 2023 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 02 February 2024 |
| First version publication date | 02 February 2024 |

Trial information

Trial identification

| | |
|-----------------------|-----------------|
| Sponsor protocol code | NLX-112-DYS-101 |
|-----------------------|-----------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05148884 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Neurolix SAS |
| Sponsor organisation address | 2 rue Georges Charpak, L'Arobase Le Causse Espace d'Entreprises, Labruguiere, France, FR-81290 |
| Public contact | CEO, Neurolix SAS, anewmantancredi@neurolix.com |
| Scientific contact | CEO, Neurolix SAS, anewmantancredi@neurolix.com |

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 | 18 January 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 18 January 2023 |
| Global end of trial reached? | Yes |
| Global end of trial date | 18 January 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of NLX-112, titrated up to a maximum of 2 mg/day, compared to placebo during eight weeks of daily treatment in PD patients with LID.

Protection of trial subjects:

The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and are compliant with the International Conference of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) E6 (R2) guidance, the EU Clinical Trials Directive 2001/20/EC, and applicable local regulatory requirements. It was the responsibility of each Investigator or an authorized associate to give each potential study patient adequate verbal and written information before any study specific assessments were performed.

The information included the objectives and the procedures of the study as well as any risks or inconvenience involved. It was emphasized that participation in the study was voluntary and that the patient could withdraw from participation at any time and for any reason, without any prejudice. All patients were given the opportunity to ask questions about the study and were given sufficient time to consider participation before signing the Informed consent form (ICF). Before performing any study-related procedures, the ICF was signed and personally dated by the patient and the Investigator. A copy of the patient information including the signed ICF was provided to the patient. Documentation of the discussion and the date of informed consent were recorded in the source documentation and in the electronic case report form (eCRF).

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 09 November 2021 |
| 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 | Sweden: 27 |
| Worldwide total number of subjects | 27 |
| EEA total number of subjects | 27 |

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) | 12 |
| From 65 to 84 years | 14 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details:

Potential participants in the study were identified according to the routines of the clinical study sites. Patients were recruited at 5 clinical sites, with a planned average of 4 to 6 patients per site.

Pre-assignment

Screening details:

A total of 35 patients were screened and 27 were randomized and dosed in the study. Eighteen patients were allocated to treatment with NLX-112 and 9 were allocated to placebo. Twenty-three patients, 15 on NLX-112 and 8 on placebo, completed the study.

Period 1

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

Blinding implementation details:

This was a double-blind study and the allocation of treatments was not disclosed until a clean file had been declared and the database had been locked. The IMP and the placebo were identical in appearance and taste.

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | NLX-112 |

Arm description:

Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received NLX-112.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | NLX-112 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Patients self-administered NLX-112 2 times each day, once in the morning and once in the evening, according to a dosing instruction sheet. Tablets were to be taken with approximately 240 mL water during a meal.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received placebo.

| | |
|--|----------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Patients self-administered placebo 2 times each day, once in the morning and once in the evening, according to a dosing instruction sheet. Tablets were to be taken with approximately 240 mL water during a meal.

| Number of subjects in period 1 | NLX-112 | Placebo |
|---------------------------------------|---------|---------|
| Started | 18 | 9 |
| Completed | 15 | 8 |
| Not completed | 3 | 1 |
| Consent withdrawn by subject | 3 | - |
| Deep brain stimulation operation | - | 1 |

Baseline characteristics

Reporting groups

| | |
|--|---------|
| Reporting group title | NLX-112 |
| Reporting group description: Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received NLX-112. | |
| Reporting group title | Placebo |
| Reporting group description: Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received placebo. | |

| Reporting group values | NLX-112 | Placebo | Total |
|---|---------|---------|-------|
| Number of subjects | 18 | 9 | 27 |
| 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) | 8 | 4 | 12 |
| From 65-84 years | 9 | 5 | 14 |
| 85 years and over | 1 | 0 | 1 |
| Age continuous Units: years | | | |
| arithmetic mean | 65.7 | 64.6 | |
| standard deviation | ± 9.7 | ± 6.3 | - |
| Gender categorical Units: Subjects | | | |
| Female | 8 | 4 | 12 |
| Male | 10 | 5 | 15 |

End points

End points reporting groups

| | |
|--|---------|
| Reporting group title | NLX-112 |
| Reporting group description: | |
| Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received NLX-112. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received placebo. | |

Primary: Frequency, intensity and seriousness of AEs

| | |
|---|--|
| End point title | Frequency, intensity and seriousness of AEs ^[1] |
| End point description: | |
| Number of patients with Adverse events (AEs) divided into categories of severity/intensity (grade 1 to grade 5 following the common terminology criteria for AEs (CTCAE) v5.0) and assessed relationship to IMP (unlikely, possibly or probably related). | |
| End point type | Primary |
| End point timeframe: | |
| AEs (including SAEs) were collected from the start of IMP administration until the end-of-study visit. | |

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: Per protocol, the end-point is reported using descriptive statistics only.

| End point values | NLX-112 | Placebo | | |
|---|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 9 | | |
| Units: Number of subjects | | | | |
| Any AE | 16 | 7 | | |
| Any SAE | 0 | 1 | | |
| Congenital Anomaly or Birth Defect | 0 | 0 | | |
| Persistent/Significant Disability/Incapacity | 0 | 0 | | |
| Requires or Prolongs Hospitalization | 0 | 1 | | |
| Is Life Threatening | 0 | 0 | | |
| Other Medically Important Serious Event | 0 | 0 | | |
| Any AE leading to withdrawal from study | 1 | 0 | | |
| Any AE leading to death | 0 | 0 | | |
| Causality - Unlikely Related | 11 | 4 | | |
| Causality - Possibly Related | 15 | 5 | | |
| Causality - Probably Related | 3 | 3 | | |
| Action taken with study drug - Dose Not Changed | 12 | 6 | | |
| Action taken with study drug - Dose Reduced | 4 | 3 | | |
| Action taken with study drug - Drug Interrupted | 0 | 1 | | |
| Action taken with study drug - Not Applicable | 5 | 2 | | |

| | | | | |
|-----------------------------|----|---|--|--|
| Severity - Mild | 14 | 7 | | |
| Severity - Moderate | 10 | 4 | | |
| Severity - Severe | 0 | 1 | | |
| Severity - Life-Threatening | 0 | 0 | | |
| Severity - Death | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Clinically significant (CS) changes from baseline in electrocardiogram (ECG)

| | |
|-----------------|---|
| End point title | Clinically significant (CS) changes from baseline in electrocardiogram (ECG) ^[2] |
|-----------------|---|

End point description:

Number of patients with clinically significant changes from baseline in Electrocardiogram (Rate, PR interval, QRS duration, QT, QTcB, and QTcF). Any abnormalities were specified and documented as either clinically significant or not clinically significant.

All ECGs were interpreted as normal or abnormal, not clinically significant by the Investigator at screening, baseline (Visit 2) and all subsequent post-dose visits to the clinics. There were no clinically relevant changes from baseline, and no obvious differences between the treatment groups, either in terms of overall ECG evaluations or change from baseline in individual ECG parameters.

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

End point timeframe:

Visit 1 (Screening), Visit 2 (Baseline, Day 1), Visit 4 (Clinic Safety Visit, Day 14), Visit 5 (Clinic Safety Visit, Day 21), Visit 6 (Clinic Efficacy Visit, Day 28), Visit 7 (Clinic Efficacy Visit, Day 42) and Visit 9 (Follow-up Clinic Visit, Day 70).

Notes:

[2] - 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: Per protocol, the end-point is reported using descriptive statistics only.

| End point values | NLX-112 | Placebo | | |
|---|-------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 ^[3] | 9 ^[4] | | |
| Units: Number of patients with CS changes | 0 | 0 | | |

Notes:

[3] - Full analysis set.

[4] - Full analysis set.

Statistical analyses

No statistical analyses for this end point

Primary: Clinically significant (CS) changes from baseline in vital signs

| | |
|-----------------|---|
| End point title | Clinically significant (CS) changes from baseline in vital signs ^[5] |
|-----------------|---|

End point description:

Number of patients with clinically significant changes from baseline in vital signs (Systolic blood pressure (mmHg), diastolic blood pressure (mmHg), Heart rate, respiratory rate, body temperature). Any vital signs outside the normal ranges at each site were judged as either not clinically significant or clinically significant.

There were no clinically relevant changes from baseline in mean vital signs parameters over time and no clinically relevant differences in any vital signs parameter between the active treatment group or the

placebo group as assessed by the Investigator. Eighteen of the 27 randomized patients, 12 on NLX-112 and 6 on placebo, had abnormal vital signs assessed as not clinically significant on one or more occasions during the study. Of these, 2 patients, both on NLX-112, had abnormal vital signs assessed as significant.

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

End point timeframe:

Visit 1 (Screening), Visit 2 (Baseline, Day 1), Visit 4 (Clinic Safety Visit, Day 14), Visit 5 (Clinic Safety Visit, Day 21), Visit 6 (Clinic Efficacy Visit, Day 28), Visit 7 (Clinic Efficacy Visit, Day 42) and Visit 9 (Follow-up Clinic Visit, Day 70).

Notes:

[5] - 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: Per protocol, the end-point is reported using descriptive statistics only.

| End point values | NLX-112 | Placebo | | |
|---|-------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 ^[6] | 9 ^[7] | | |
| Units: Number of patients with CS changes | 2 | 0 | | |

Notes:

[6] - Full analysis set.

[7] - Full analysis set.

Statistical analyses

No statistical analyses for this end point

Primary: Clinically significant (CS) changes from baseline in safety laboratory parameters

| | |
|-----------------|--|
| End point title | Clinically significant (CS) changes from baseline in safety laboratory parameters ^[8] |
|-----------------|--|

End point description:

Number of patients with clinically significant changes from baseline in safety laboratory parameters. Any lab values outside the normal ranges were judged as not clinically significant or clinically significant. There were no clinically relevant changes from baseline in mean clinical chemistry, hematology, coagulation or urinalysis parameters over time and no clinically relevant differences in any laboratory parameter between the active treatment group or the placebo group as assessed by the Investigator. All 27 randomized patients had abnormal laboratory values on one or more occasions over the course of the study. A majority of the abnormal laboratory values were assessed as not clinically significant. No coagulation parameter was assessed as abnormal. Three patients had abnormal laboratory values assessed as clinically significant, which in 2 cases were reported as AEs (inflammatory marker increased and hyperglycemia, both assessed as unrelated to treatment with NLX-112).

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

End point timeframe:

Visit 1 (Screening), Visit 2 (Baseline, Day 1), Visit 4 (Clinic Safety Visit, Day 14), Visit 5 (Clinic Safety Visit, Day 21), Visit 6 (Clinic Efficacy Visit, Day 28), Visit 7 (Clinic Efficacy Visit, Day 42) and Visit 9 (Follow-up Clinic Visit, Day 70).

Notes:

[8] - 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: Per protocol, the end-point is reported using descriptive statistics only.

| End point values | NLX-112 | Placebo | | |
|---|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 ^[9] | 9 ^[10] | | |
| Units: Number of patients with CS changes | 2 | 1 | | |

Notes:

[9] - Full analysis set.

[10] - Full analysis set.

Statistical analyses

No statistical analyses for this end point

Primary: Clinically significant changes (CS) from baseline in physical examinations

| | |
|-----------------|--|
| End point title | Clinically significant changes (CS) from baseline in physical examinations ^[11] |
|-----------------|--|

End point description:

Number of clinically significant changes in physical examination investigated by general appearance, head, ears, eyes, nose, throat, neck, skin, cardiovascular system, respiratory system, abdominal system, and nervous system. Any abnormalities were specified and documented as either clinically significant or not clinically significant.

There were no clinically relevant changes from baseline (screening) to Visit 9 (Day 70±7 days) in physical examination findings between the active treatment group or the placebo group as assessed by the Investigator. Fourteen of the 27 randomized patients had a physical examination assessed as abnormal, clinically significant for one or more organ system at either the screening visit (Visit 1) or Visit 9 or both. Clinically significant findings were most commonly associated with the nervous system and the underlying PD (12 patients, 8 on NLX-112 and 4 on placebo) and were observed both at screening and at Visit 9 (10 patients).

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

End point timeframe:

Visit 1 (Screening) and Visit 9 (Follow-up Clinic Visit, Day 70).

Notes:

[11] - 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: Per protocol, the end-point is reported using descriptive statistics only.

| End point values | NLX-112 | Placebo | | |
|---|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 ^[12] | 9 ^[13] | | |
| Units: Number of patients with CS changes | 8 | 4 | | |

Notes:

[12] - Full analysis set.

[13] - Full analysis set.

Statistical analyses

No statistical analyses for this end point

Primary: Suicidal ideation/behavior as assessed by the Columbia Suicide Severity Rating Scale (C-SSRS)

| | |
|-----------------|---|
| End point title | Suicidal ideation/behavior as assessed by the Columbia Suicide Severity Rating Scale (C-SSRS) ^[14] |
|-----------------|---|

End point description:

Number of patients with changes from baseline in suicidal ideation/behavior as assessed by C-SSRS questionnaire with no total score summation. The scale contains 6 "yes" or "no" questions in which respondents were asked to indicate whether they have experienced several thoughts or feelings relating

to suicide over the past month and behavior over their lifetime and past 3 months. Each question addresses a different component of the respondent's suicide ideation severity and behavior. Q1: wish to be dead, Q2: non-specific suicidal thoughts, Q3-5: more specific suicidal thoughts and intent to act, Q6: suicidal behavior over the respondent's lifetime and past 3 months, If the respondent answered "yes" to Q2, he/she was instructed to answer Q 3-5. If the respondent answered "no" to Q2, he/she could skip to Q6.

No patient indicated a change in suicidal ideation/behavior from baseline until Visit 9 (Day 70±7 days).

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

End point timeframe:

The baseline scale was used at screening (Visit 1) and the follow-up scale at all subsequent visits (Visit 2, 4-7, 9)

Notes:

[14] - 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: Per protocol, the end-point is reported using descriptive statistics only.

| End point values | NLX-112 | Placebo | | |
|--|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 ^[15] | 9 ^[16] | | |
| Units: Number of patients with changes | 0 | 0 | | |

Notes:

[15] - Full analysis set.

[16] - Full analysis set.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at the final efficacy clinic visit (Day 42), after a 150% L-DOPA dose challenge, in the Unified Dyskinesia Rating Scale (UDysRS) total score - Absolute change from baseline

| | |
|-----------------|---|
| End point title | Change from baseline at the final efficacy clinic visit (Day 42), after a 150% L-DOPA dose challenge, in the Unified Dyskinesia Rating Scale (UDysRS) total score - Absolute change from baseline |
|-----------------|---|

End point description:

The UDysRS is a rating instrument designed to assess the core features of dyskinesia in PD. The UDysRS consists of 4 parts:

- Part 1, historical disability with regard to the patient's perceptions of the impact on activities of ADL of on-dyskinesia.
- Part 2, historical disability with regard to the patient's perceptions of the impact on ADL of off-dystonia.
- Part 3, objective impairment, which assesses severity of dyskinesia, affected body parts, and type of impairment (choreic vs. dystonic).
- Part 4, objective disability, based on an evaluation of Part 3 activities.

Each item in the UDysRS was scored from 0 to 4, with a possible maximum total score of 104.

The UDysRS Parts 3 and 4 were repeated 3 times after each L-DOPA challenge, 30 minutes apart, and were hence performed approximately 30, 60 and 90 minutes after each challenge.

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

End point timeframe:

At baseline (Day 1, Visit 2), and Day 42 (Visits 7), starting approximately 30 minutes after the L-DOPA challenge.

| End point values | NLX-112 | Placebo | | |
|--------------------------------------|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[17] | 7 ^[18] | | |
| Units: UDysRS total score | | | | |
| arithmetic mean (standard deviation) | | | | |
| Visit 2 Baseline | 31.6 (± 9.7) | 39.9 (± 14.2) | | |
| Visit 7 Clinic Efficacy Visit | -6.3 (± 7.0) | -2.4 (± 9.7) | | |

Notes:

[17] - Per protocol analysis set.

[18] - Per protocol analysis set.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in UDysRS total score at Day 28, after a 150% L-DOPA dose challenge - Absolute change from baseline

| | |
|-----------------|--|
| End point title | Change from baseline in UDysRS total score at Day 28, after a 150% L-DOPA dose challenge - Absolute change from baseline |
|-----------------|--|

End point description:

The UDysRS is a rating instrument designed to assess the core features of dyskinesia in PD. The UDysRS consists of 4 parts:

- Part 1, historical disability with regard to the patient's perceptions of the impact on activities of ADL of on-dyskinesia.
- Part 2, historical disability with regard to the patient's perceptions of the impact on ADL of off-dystonia.
- Part 3, objective impairment, which assesses severity of dyskinesia, affected body parts, and type of impairment (choreic vs. dystonic).
- Part 4, objective disability, based on an evaluation of Part 3 activities.

Each item in the UDysRS was scored from 0 to 4, with a possible maximum total score of 104.

The UDysRS Parts 3 and 4 were repeated 3 times after each L-DOPA challenge, 30 minutes apart, and were hence performed approximately 30, 60 and 90 minutes after each challenge.

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

End point timeframe:

At baseline (Day 1, Visit 2) and Day 28 (Visits 6), starting approximately 30 minutes after the L-DOPA challenge.

| End point values | NLX-112 | Placebo | | |
|--------------------------------------|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[19] | 7 ^[20] | | |
| Units: UDysRS total score | | | | |
| arithmetic mean (standard deviation) | | | | |
| Visit 2 Baseline | 31.6 (± 9.7) | 39.9 (± 14.2) | | |
| Visit 6 Clinic Efficacy Visit | -4.1 (± 9.3) | -2.0 (± 4.9) | | |

Notes:

[19] - Per protocol analysis set.

[20] - Per protocol analysis set.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in total objective score (Parts 3, 4) of the UDysRS at Day 28 and Day 42, after a 150% L-DOPA dose challenge - Absolute change from baseline

| | |
|-----------------|---|
| End point title | Change from baseline in total objective score (Parts 3, 4) of the UDysRS at Day 28 and Day 42, after a 150% L-DOPA dose challenge - Absolute change from baseline |
|-----------------|---|

End point description:

The UDysRS is a rating instrument designed to assess the core features of dyskinesia in PD. The UDysRS consists of 4 parts:

- Part 1, historical disability with regard to the patient's perceptions of the impact on activities of ADL of on-dyskinesia.
- Part 2, historical disability with regard to the patient's perceptions of the impact on ADL of off-dystonia.
- Part 3, objective impairment, which assesses severity of dyskinesia, affected body parts, and type of impairment (choreic vs. dystonic).
- Part 4, objective disability, based on an evaluation of Part 3 activities.

Each item in the UDysRS was scored from 0 to 4, with a possible maximum total score of 104.

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

End point timeframe:

At baseline (Day 1, Visit 2), Day 28 and Day 42 (Visits 6 and 7), starting approximately 30 minutes after the L-DOPA challenge.

| End point values | NLX-112 | Placebo | | |
|--------------------------------------|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[21] | 7 ^[22] | | |
| Units: UDysRS total score | | | | |
| arithmetic mean (standard deviation) | | | | |
| Visit 2 Baseline | 15.5 (± 6.2) | 18.1 (± 7.9) | | |
| Visit 6 Clinic Efficacy Visit | -1.7 (± 4.3) | -1.0 (± 1.8) | | |
| Visit 7 Clinic Efficacy Visit | -3.1 (± 4.2) | -0.1 (± 3.8) | | |

Notes:

[21] - Per protocol analysis set.

[22] - Per protocol analysis set.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in ON Time Without Troublesome Dyskinesia (ON Without Dyskinesia plus ON With Non-troublesome Dyskinesia) based on a PD Home Dyskinesia Diary - Absolute change from baseline

| | |
|-----------------|--|
| End point title | Change from baseline in ON Time Without Troublesome Dyskinesia (ON Without Dyskinesia plus ON With Non-troublesome Dyskinesia) based on a PD Home Dyskinesia Diary - Absolute change from baseline |
|-----------------|--|

End point description:

A PD Home Dyskinesia Diary (electronic) as completed by the patient and/or caregiver with concordance in ON time with dyskinesia between study staff and patient. The diary was integrated in the Kinesia 360 wearable dyskinesia assessment system and was based on the PD Home Diary developed by Hauser et al 2004. The diary was used to score 5 different conditions in 30-minute time intervals during 2x24 hours prior to Visit 2, Visit 6 and Visit 7:

- ASLEEP;
- OFF;
- ON (i.e., adequate control of PD symptoms) without dyskinesia;
- ON with non-troublesome dyskinesia;
- ON with troublesome dyskinesia.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| The patient and/or caregiver completed a PD Home Dyskinesia eDiary diary in 30-minute time intervals during 2x24 hours prior to baseline (Visit 2), and during 4x24 hours prior to Day 28 (Visit 6) and Day 42 (Visit 7). | |

| End point values | NLX-112 | Placebo | | |
|--------------------------------------|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[23] | 7 ^[24] | | |
| Units: ON and OFF ratio | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 0.576 (± 0.199) | 0.548 (± 0.192) | | |
| Titration | 0.0569 (± 0.158) | 0.0245 (± 0.135) | | |
| Steady-State | 0.0523 (± 0.193) | 0.0335 (± 0.154) | | |

Notes:

[23] - Per protocol analysis set.

Titration n = 13, Steady-State n = 12

[24] - Per protocol analysis set.

Titration n = 6, Steady-State n = 6

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Unified Parkinson's Disease Rating Scale (UPDRS) scores (Part III, motor examination) - Absolute change from baseline

| | |
|-----------------|---|
| End point title | Change from baseline in Unified Parkinson's Disease Rating Scale (UPDRS) scores (Part III, motor examination) - Absolute change from baseline |
|-----------------|---|

End point description:

The UPDRS is one of the most widely-used rating scales employed in the assessment of PD. The UPDRS consists of 4 parts:

- Part I assesses non-motor experiences of daily living, such as cognitive impairment and depressed mood.
- Part II assesses motor experiences of daily living, such as speech and eating tasks.
- Part III is a motor examination conducted by the clinician, including assessments of symptoms such as rigidity and tremor.
- Part IV is an assessment of motor complications, such as time spent with dyskinesia and functional impact of dyskinesias.

Each item in the UPDRS was scored from 0 to 4, and the individual scores were summed to give a total score that indicates the severity of the disease, with a score of 0 indicating no disability and a score of 199 being the most severe (indicating total disability).

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At baseline (Day 1, Visit 2), Day 28 (Visit 6), Day 42 (Visit 7) and Day 70 (Visit 9). | |

| End point values | NLX-112 | Placebo | | |
|--------------------------------------|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[25] | 7 ^[26] | | |
| Units: UPDRS total score | | | | |
| arithmetic mean (standard deviation) | | | | |
| Visit 2 Baseline | 17.5 (± 9.4) | 17.0 (± 10.3) | | |
| Visit 6 Clinic Efficacy Visit | -3.7 (± 4.7) | 1.3 (± 6.9) | | |
| Visit 7 Clinic Efficacy Visit | -3.7 (± 4.6) | 0.1 (± 8.2) | | |
| Visit 9 Follow-up Clinic Visit | -2.7 (± 5.5) | -2.4 (± 2.9) | | |

Notes:

[25] - Per protocol analysis set.

[26] - Per protocol analysis set.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in UPDRS combined scores (Parts I, II, III and IV) - Absolute change from baseline

| | |
|-----------------|---|
| End point title | Change from baseline in UPDRS combined scores (Parts I, II, III and IV) - Absolute change from baseline |
|-----------------|---|

End point description:

The UPDRS is one of the most widely-used rating scales employed in the assessment of PD. The UPDRS consists of 4 parts:

- Part I assesses non-motor experiences of daily living, such as cognitive impairment and depressed mood.
- Part II assesses motor experiences of daily living, such as speech and eating tasks.
- Part III is a motor examination conducted by the clinician, including assessments of symptoms such as rigidity and tremor.
- Part IV is an assessment of motor complications, such as time spent with dyskinesia and functional impact of dyskinesias.

Each item in the UPDRS was scored from 0 to 4, and the individual scores were summed to give a total score that indicates the severity of the disease, with a score of 0 indicating no disability and a score of 199 being the most severe (indicating total disability).

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

End point timeframe:

At baseline (Day 1, Visit 2), Day 28 (Visit 6), Day 42 (Visit 7) and Day 70 (Visit 9).

| End point values | NLX-112 | Placebo | | |
|--------------------------------------|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[27] | 7 ^[28] | | |
| Units: UPDRS total score | | | | |
| arithmetic mean (standard deviation) | | | | |
| Visit 2 Baseline | 37.0 (± 13.3) | 41.3 (± 15.0) | | |
| Visit 6 Clinic Efficacy Visit | -6.5 (± 7.6) | -3.6 (± 7.0) | | |
| Visit 7 Clinic Efficacy Visit | -5.7 (± 6.0) | -3.9 (± 9.3) | | |
| Visit 9 Follow-up Clinic Visit | -4.4 (± 9.0) | -7.3 (± 5.4) | | |

Notes:

[27] - Per protocol analysis set.

[28] - Per protocol analysis set.

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Global Impression of Change (CGI-C) in overall PD symptoms

| | |
|-----------------|---|
| End point title | Clinical Global Impression of Change (CGI-C) in overall PD symptoms |
|-----------------|---|

End point description:

The CGI-C is a clinician-oriented scale that assesses the total improvement in the patient's condition relative to the clinical global impression of severity (CGI-S) scale conducted at baseline. The CGI-C rates the patient's condition from 0 to 7, with a rating of 0 indicating "no assessment", a rating of 1 indicating "very much better", and a rating of 7 indicating "very much worse".

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

End point timeframe:

Patients rated their global condition using CGI-S at baseline (Day 1, Visit 2) and CGI-C at Day 28 (Visit 6) and Day 42 (Visit 7).

| End point values | NLX-112 | Placebo | | |
|--|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[29] | 7 ^[30] | | |
| Units: Number of subjects | | | | |
| Visit 2 Baseline - Normal, not at all ill | 3 | 2 | | |
| Visit 2 Baseline - Moderately ill | 8 | 2 | | |
| Visit 2 Baseline - Markedly ill | 3 | 2 | | |
| Visit 2 Baseline - Severely ill | 1 | 1 | | |
| Visit 6 Clinic Efficacy Visit - Much improved | 2 | 2 | | |
| Visit 6 Clinic Efficacy Visit - Minimally improved | 3 | 0 | | |
| Visit 6 Clinic Efficacy Visit - No change | 9 | 4 | | |
| Visit 6 Clinic Efficacy Visit - Minimally worse | 1 | 1 | | |
| Visit 7 Clinic Efficacy Visit - Very much improved | 1 | 0 | | |
| Visit 7 Clinic Efficacy Visit - Much improved | 4 | 1 | | |
| Visit 7 Clinic Efficacy Visit - Minimally improved | 3 | 1 | | |
| Visit 7 Clinic Efficacy Visit - No change | 6 | 5 | | |
| Visit 7 Clinic Efficacy Visit - Minimally worse | 1 | 0 | | |

Notes:

[29] - Per protocol analysis set.

[30] - Per protocol analysis set.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in dyskinesia scores measured by the Kinesia 360 (Great Lakes Neurotechnologies, Inc) wearable dyskinesia assessment system - Absolute change from baseline

| | |
|-----------------|--|
| End point title | Change from baseline in dyskinesia scores measured by the Kinesia 360 (Great Lakes Neurotechnologies, Inc) wearable dyskinesia assessment system - Absolute change from baseline |
|-----------------|--|

End point description:

The Kinesia 360 (Great Lakes Neurotechnologies, Inc) wearable dyskinesia assessment system was used to monitor dyskinesias. The Kinesia 360 motor assessment system is intended to provide a low burden method for remote, continuous measurement of patient symptoms. Sensors worn on the wrist and ankle combined with a mobile application continuously record data for assessment of tremor, slowness, dyskinesia and mobility. Data from the motion sensors was uploaded to the Kinesia Web Portal and algorithms were used to detect symptoms and calculate severity scores every 2 minutes on a scale shown to be highly correlated with clinician ratings. Sensors recorded data all day and were recharged overnight for extended home use.

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

End point timeframe:

Wearable data collection of dyskinesias took place during a 2-day period prior to the baseline visit (Day 1, Visit 2) and a 4-day period prior to Day 28 (Visit 6) and Day 42 (Visit 7).

| End point values | NLX-112 | Placebo | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 ^[31] | 7 ^[32] | | |
| Units: Dyskinesia detect scores | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 0.1807 (± 0.1955) | 0.2855 (± 0.3322) | | |
| Titration | -0.06517 (± 0.06722) | -0.009172 (± 0.1353) | | |
| Steady-State | -0.009327 (± 0.1243) | -0.01630 (± 0.3166) | | |

Notes:

[31] - Per protocol analysis set.

Baseline n = 12, Titration n = 8, Steady-State n = 6

[32] - Per protocol analysis set.

Baseline n = 5, Titration n = 3, Steady-State n = 3

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs (including SAEs) were collected from the start of IMP administration until the end-of-study visit.

Adverse event reporting additional description:

The grading of the severity/intensity (grade 1 to grade 5) of AEs followed the common terminology criteria for AEs (CTCAE) v5.0 [24]. AEs were assessed as unlikely, possibly or probably related to the IMP.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | NLX-112 |
|-----------------------|---------|

Reporting group description:

Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received NLX-112.

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Patients were randomized to receive either active treatment with NLX-112 or placebo. This arm represents the patients that received placebo.

| Serious adverse events | NLX-112 | Placebo | |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 9 (11.11%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Nervous system disorders | | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 9 (11.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | NLX-112 | Placebo | |
|---|------------------|----------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 16 / 18 (88.89%) | 7 / 9 (77.78%) | |
| Vascular disorders | | | |

| | | | |
|---|----------------------|---------------------|--|
| Hypertension subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 9 (11.11%) 1 | |
| Orthostatic hypotension subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | 1 / 9 (11.11%) 1 | |
| Systolic hypertension subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Surgical and medical procedures Cataract operation subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 2 | 0 / 9 (0.00%) 0 | |
| General disorders and administration site conditions Condition aggravated subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Fatigue subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | 2 / 9 (22.22%) 3 | |
| Psychiatric disorders Apathy subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Depression subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 9 (11.11%) 1 | |
| Dissociation subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | 0 / 9 (0.00%) 0 | |
| Hallucination subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Illusion subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 9 (11.11%) 1 | |

| | | | |
|--|-----------------|----------------|--|
| Insomnia | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 0 / 9 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Irritability | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Rapid eye movement sleep behavior disorder | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sleep disorder | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Stress | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Investigations | | | |
| Inflammatory marker increased | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 0 / 9 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Incorrect dose administered | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lip injury | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Product communication issue | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiac disorders | | | |
| Palpitations | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|-----------------------------|-----------------|----------------|--|
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 1 / 9 (11.11%) | |
| occurrences (all) | 2 | 1 | |
| Dyskinesia | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 0 / 9 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Headache | | | |
| subjects affected / exposed | 3 / 18 (16.67%) | 2 / 9 (22.22%) | |
| occurrences (all) | 4 | 3 | |
| On and off phenomenon | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Parkinsonism | | | |
| subjects affected / exposed | 3 / 18 (16.67%) | 3 / 9 (33.33%) | |
| occurrences (all) | 3 | 7 | |
| Parosmia | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Restless legs syndrome | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 0 / 9 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 9 (11.11%) | |
| occurrences (all) | 1 | 1 | |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 9 (11.11%) | |
| occurrences (all) | 0 | 1 | |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 9 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vertigo | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 1 / 9 (11.11%) | |
| occurrences (all) | 2 | 1 | |
| Eye disorders | | | |

| | | | |
|---|----------------------|---------------------|--|
| Binocular eye movement disorder subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Dry eye subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 9 (11.11%) 1 | |
| Erythema of eyelid subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Eye pain subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 9 (11.11%) 1 | |
| Swelling of eyelid subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Gastrointestinal disorders | | | |
| Diarrhea subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Dry mouth subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Gastritis subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Nausea subjects affected / exposed occurrences (all) | 4 / 18 (22.22%) 4 | 0 / 9 (0.00%) 0 | |
| Oral pain subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Vomiting subjects affected / exposed occurrences (all) | 2 / 18 (11.11%) 2 | 1 / 9 (11.11%) 1 | |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|--|---|---|--|
| Alopecia subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 9 (11.11%) 1 | |
| Renal and urinary disorders Micturition urgency subjects affected / exposed occurrences (all) Pollakiuria subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Muscle spasms subjects affected / exposed occurrences (all) Musculoskeletal stiffness subjects affected / exposed occurrences (all) Neck pain subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 2 / 18 (11.11%) 2 1 / 18 (5.56%) 1 1 / 18 (5.56%) 1 0 / 18 (0.00%) 0 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 | |
| Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Influenza subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 1 / 18 (5.56%) 1 | 1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 | |

| | | | |
|---|---------------------|---------------------|--|
| Nasopharyngitis subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 2 / 9 (22.22%) 2 | |
| Respiratory tract infection subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 9 (11.11%) 1 | |
| Urinary tract infection subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 2 | 0 / 9 (0.00%) 0 | |
| Metabolism and nutrition disorders Hyperglycemia subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 9 (0.00%) 0 | |

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