



Clinical trial results:

A randomized, double-blind, cross-over, placebo-controlled, multi-center, Phase 2a study to assess the safety and efficacy of BAY 2395840 in patients with diabetic neuropathic pain

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2021-001392-17 |
| Trial protocol | HU CZ ES SK DE |
| Global end of trial date | 21 November 2022 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 26 November 2023 |
| First version publication date | 26 November 2023 |

Trial information

Trial identification

| | |
|-----------------------|------------------|
| Sponsor protocol code | BAY2395840/19636 |
|-----------------------|------------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05219812 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Bayer AG |
| Sponsor organisation address | Kaiser-Wilhelm-Allee, Leverkusen, Germany, D-51368 |
| Public contact | Therapeutic Area Head, Bayer AG, +46 30 300139003, clinical-trials-contact@bayer.com |
| Scientific contact | Therapeutic Area Head, Bayer AG, +46 30 300139003, clinical-trials-contact@bayer.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 | 21 November 2022 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 21 November 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the efficacy of BAY2395840 on pain associated with diabetic neuropathic pain (DNP) as compared with placebo.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and the International Council for Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent was read by and explained to all the subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 16 February 2022 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Czechia: 19 |
| Country: Number of subjects enrolled | Hungary: 11 |
| Country: Number of subjects enrolled | Slovakia: 20 |
| Country: Number of subjects enrolled | Germany: 21 |
| Country: Number of subjects enrolled | Spain: 4 |
| Country: Number of subjects enrolled | United Kingdom: 5 |
| Worldwide total number of subjects | 80 |
| EEA total number of subjects | 75 |

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 | 0 |

| | |
|---------------------------|----|
| months) | |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 33 |
| From 65 to 84 years | 47 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Study was conducted at 29 centers in 6 countries between 16 FEB 2022 (first participant first visit) and 21 NOV 2022 (last participant last visit).

Pre-assignment

Screening details:

133 subjects were screened in the study, 81 subjects were randomized (1 subject never received treatment). Of those, 52 subjects did not randomize to the study treatment (48 were screening failures, 3 decided not to participate, 1 failed screen due to other reasons).

Period 1

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

Arms

| | |
|------------------------------|----------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Dosage A of BAY2395840 - Placebo |

Arm description:

Subjects received dosage A of BAY2395840 in period 1, and received placebo in period 2.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | BAY2395840 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Dosage A, tablet, oral administration

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

Dosage and administration details:

once daily, tablet, oral administration

| | |
|------------------|----------------------------------|
| Arm title | Placebo - Dosage A of BAY2395840 |
|------------------|----------------------------------|

Arm description:

Subjects received placebo in period 1, and received dosage A of BAY2395840 in period 2.

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

Dosage and administration details:

once daily, tablet, oral administration

| | |
|--|------------|
| Investigational medicinal product name | BAY2395840 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Dosage A, tablet, oral administration

| Number of subjects in period 1 | Dosage A of BAY2395840 - Placebo | Placebo - Dosage A of BAY2395840 |
|--------------------------------|--|-------------------------------------|
| | | |
| Started | 40 | 40 |
| Period 1 | 40 | 40 |
| Run-in phase | 39 | 39 |
| Period 2 | 39 | 39 |
| Completed | 37 | 38 |
| Not completed | 3 | 2 |
| Adverse event, serious fatal | 1 | - |
| Consent withdrawn by subject | 1 | - |
| Adverse event, non-fatal | 1 | 1 |
| Protocol deviation | - | 1 |

Baseline characteristics

Reporting groups

| | |
|---|----------------------------------|
| Reporting group title | Dosage A of BAY2395840 - Placebo |
| Reporting group description: Subjects received dosage A of BAY2395840 in period 1, and received placebo in period 2. | |
| Reporting group title | Placebo - Dosage A of BAY2395840 |
| Reporting group description: Subjects received placebo in period 1, and received dosage A of BAY2395840 in period 2. | |

| Reporting group values | Dosage A of BAY2395840 - Placebo | Placebo - Dosage A of BAY2395840 | Total |
|---|----------------------------------|----------------------------------|-------|
| Number of subjects | 40 | 40 | 80 |
| Age Categorical Units: Subjects | | | |
| Age Continuous Units: years arithmetic mean standard deviation | 65.2 ± 10.5 | 64.4 ± 10.6 | - |
| Gender Categorical Units: Subjects | | | |
| Female | 21 | 19 | 40 |
| Male | 19 | 21 | 40 |

End points

End points reporting groups

| | |
|---|----------------------------------|
| Reporting group title | Dosage A of BAY2395840 - Placebo |
| Reporting group description: Subjects received dosage A of BAY2395840 in period 1, and received placebo in period 2. | |
| Reporting group title | Placebo - Dosage A of BAY2395840 |
| Reporting group description: Subjects received placebo in period 1, and received dosage A of BAY2395840 in period 2. | |
| Subject analysis set title | Safety analysis set (SAF) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Subjects who took at least one dose of study intervention. Of 81 randomized subjects, 80 subjects (98.8%, 40 per treatment sequence) were valid for SAF since 1 subject never received study intervention. | |
| Subject analysis set title | Per protocol set (PPS) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: All subjects in FAS without any validity finding impacting interpretation of study results were available. PPS included 78 subjects (39 per treatment sequence) which was 96.3% of all randomized subjects. | |
| Subject analysis set title | Dosage A of BAY2395840 in PPS |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects treated with BAY2395840 in the PPS. in Group 1 (BAY2395840 - placebo treatment sequence) period 1 and in Group 2 (placebo - BAY2395840 treatment sequence) period 2. | |
| Subject analysis set title | Placebo in PPS |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects treated with placebo in the PPS. Group 1 (BAY2395840 - placebo treatment sequence) period 2 and in Group 2 (placebo - BAY2395840 treatment sequence) period 1. | |
| Subject analysis set title | Dosage A of BAY2395840 in SAF |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects treated with BAY2395840 in the SAF. Overall, 80 participants were valid for SAF. 2 participants (1 in Group 1 with BAY2395840 – placebo treatment sequence, 1 in Group 2 with placebo – BAY2395840 treatment sequence) did not enter period 2. Thus, 79 participants were treated with BAY2395840 in the SAF. | |
| Subject analysis set title | Placebo in SAF |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects treated with placebo in the SAF. Overall, 80 participants were valid for SAF. 2 participants (1 in Group 1 with BAY2395840 – placebo treatment sequence, 1 in Group 2 with placebo – BAY2395840 treatment sequence) did not enter period 2. Thus, 79 participants were treated with placebo in the SAF. | |

Primary: Change in weekly mean 24-hour average pain intensity score using the 11-point NRS from baseline to the end of intervention

| | |
|---|--|
| End point title | Change in weekly mean 24-hour average pain intensity score using the 11-point NRS from baseline to the end of intervention |
| End point description: Subjects were asked to report their average neuropathic pain severity in the past 24 hours using an 11-point NRS with 0 as "no pain" and 10 as "worst imaginable pain". NRS=Pain Numeric Rating Scale | |
| End point type | Primary |
| End point timeframe: Baseline to end of intervention (in total up to 16 weeks) | |

| End point values | Dosage A of BAY2395840 in PPS | Placebo in PPS | | |
|--------------------------------------|-------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 76 ^[1] | 75 ^[2] | | |
| Units: scores | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 | -0.33 (± 0.82) | -0.39 (± 0.86) | | |
| Week 2 | -0.44 (± 0.98) | -0.75 (± 1.13) | | |
| Week 3 | -0.67 (± 1.24) | -1.06 (± 1.30) | | |
| Week 4 | -0.93 (± 1.45) | -1.23 (± 1.44) | | |

Notes:

[1] - PPS

[2] - PPS, the analyzed subjects at Week 1 and 2 were 75, at Week 3 it was 74, and at Week 4 it was 71.

Statistical analyses

| Statistical analysis title | ANCOVA for change from baseline in NRS |
|---|--|
| Statistical analysis description: | |
| At Week 4 in period 1 and period 2, the estimated mean (SE) treatment difference for weekly mean 24-hour average NRS between BAY2395840 and placebo | |
| Comparison groups | Dosage A of BAY2395840 in PPS v Placebo in PPS |
| Number of subjects included in analysis | 151 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[3] |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.07 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.17 |
| upper limit | 0.314 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.146 |

Notes:

[3] - Database auto-calculates total number of subjects erroneously, analysed number of subjects was 78.

Secondary: Number of participants with treatment emergent adverse events

| End point title | Number of participants with treatment emergent adverse events |
|---|---|
| End point description: | |
| An AE was any untoward medical occurrence in a clinical study participant, associated with the use of study intervention, whether or not considered related to the study intervention. An SAE was defined as any AE that, at any dose: a. Results in death, b. Was life-threatening, c. Required inpatient hospitalization or prolongation of existing hospitalization, d. Resulted in persistent or significant disability/incapacity, e. Was a congenital anomaly/birth defect, etc. AE=Adverse event SAE=Serious adverse event | |
| End point type | Secondary |

End point timeframe:

From start of study intervention to 14 days after last dose (up to 13 weeks)

| End point values | Dosage A of BAY2395840 in SAF | Placebo in SAF | | |
|-----------------------------|-------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 79 ^[4] | 79 ^[5] | | |
| Units: subjects | | | | |
| Any AE | 33 | 26 | | |
| Any SAE | 2 | 2 | | |

Notes:

[4] - SAF

[5] - SAF

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Neuropathic Pain Symptom Inventory (NPSI) total score from baseline to the end of intervention

| | |
|-----------------|--|
| End point title | Change in Neuropathic Pain Symptom Inventory (NPSI) total score from baseline to the end of intervention |
|-----------------|--|

End point description:

The NPSI contained 12 items, of which five summary pain scores can be calculated: "superficial spontaneous", "deep spontaneous", "paroxysmal pain", "evoked pain", and "paresthesia/ dysesthesia". The total score was sum of the summary scores divided by 100. The 10 descriptive items used to derive the domain summary scores are each rated on an 11-point numeric rating scale (0= "no (symptom)" and 10= "worst (symptom) imaginable"); each item has a recall period of the past 24 hours. The remaining two items report how consistently pain has been present and the number of pain episodes.

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

End point timeframe:

At visit 2, visit 4, visit 6, visit 8, visit 10 and at visit 12 end of intervention (EOI)

| End point values | Dosage A of BAY2395840 in PPS | Placebo in PPS | | |
|--------------------------------------|-------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 78 ^[6] | 78 ^[7] | | |
| Units: scores | | | | |
| arithmetic mean (standard deviation) | | | | |
| Visit 4 / Visit 10 | -6.89 (± 10.53) | -5.43 (± 10.56) | | |
| Visit 6 / Visit 12 | -7.23 (± 15.10) | -5.30 (± 11.44) | | |

Notes:

[6] - Per protocol set (PPS)

[7] - Per protocol set (PPS)

Statistical analyses

| | |
|---|--|
| Statistical analysis title | ANCOVA of change on NPSI |
| Statistical analysis description: The mean difference change from baseline in the NPSI total score between BAY2395840 and placebo at Week 4 in period 1 and period 2 | |
| Comparison groups | Dosage A of BAY2395840 in PPS v Placebo in PPS |
| Number of subjects included in analysis | 156 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[8] |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -1.19 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -3.528 |
| upper limit | 1.157 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.406 |

Notes:

[8] - Database auto-calculates total number of subjects erroneously, analysed number of subjects was 78.

Secondary: Change in Patient Global Impression of Severity (PGI-S) score from baseline to the end of intervention

| | |
|---|--|
| End point title | Change in Patient Global Impression of Severity (PGI-S) score from baseline to the end of intervention |
| End point description: Subjects were asked to best describe their diabetic nerve pain symptoms on a 6-point scale in the last week scored as: "none"(1), "very mild"(2), "mild"(3), "moderate"(4), "severe"(5), or "very severe"(6). PGI-S=Patient Global Impression of Severity | |
| End point type | Secondary |
| End point timeframe: At visit 2, visit 4, visit 6, visit 8, visit 10 and at visit 12 end of intervention (EOI) | |

| End point values | Dosage A of BAY2395840 in PPS | Placebo in PPS | | |
|--------------------------------------|-------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 78 ^[9] | 78 ^[10] | | |
| Units: scores | | | | |
| arithmetic mean (standard deviation) | | | | |
| Visit 4 / Visit 10 | -0.27 (± 0.85) | -0.37 (± 0.83) | | |
| Visit 6 / Visit 12 | -0.39 (± 0.88) | -0.43 (± 0.94) | | |

Notes:

[9] - Per protocol set (PPS)

[10] - Per protocol set (PPS)

Statistical analyses

| | |
|---|---------------------------|
| Statistical analysis title | ANCOVA of change on PGI-S |
| Statistical analysis description: The estimated mean (SE) treatment difference based on PGI-S severity score between BAY2395840 and placebo at Week 4 in period 1 and period 2 | |

| | |
|---|--|
| Comparison groups | Dosage A of BAY2395840 in PPS v Placebo in PPS |
| Number of subjects included in analysis | 156 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[11] |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.07 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.131 |
| upper limit | 0.272 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.121 |

Notes:

[11] - Database auto-calculates total number of subjects erroneously, analysed number of subjects was 78.

Secondary: Number of subjects achieving a $\geq 30\%$ and a $\geq 50\%$ reduction in weekly mean 24-hour average pain intensity score (i.e. responder rates using NRS)

| | |
|-----------------|---|
| End point title | Number of subjects achieving a $\geq 30\%$ and a $\geq 50\%$ reduction in weekly mean 24-hour average pain intensity score (i.e. responder rates using NRS) |
|-----------------|---|

End point description:

Responder rates using NRS were defined as the proportion of participants with a $\geq 30\%$ and a $\geq 50\%$ reduction in weekly mean 24-hour average pain intensity score at Visit 4 in period 1 and Visit 10 in period 2. NRS=Pain Numeric Rating Scale

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

End point timeframe:

From baseline to end of intervention (in total up to 12 weeks)

| End point values | Dosage A of BAY2395840 in PPS | Placebo in PPS | | |
|---------------------------------------|-------------------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 78 ^[12] | 78 ^[13] | | |
| Units: subjects | | | | |
| Achieved $\geq 30\%$ reduction in NRS | 24 | 33 | | |
| Achieved $\geq 50\%$ reduction in NRS | 10 | 13 | | |

Notes:

[12] - Per protocol set (PPS)

[13] - Per protocol set (PPS)

Statistical analyses

| | |
|----------------------------|-----------------------------------|
| Statistical analysis title | Marginal responder rates analysis |
|----------------------------|-----------------------------------|

Statistical analysis description:

Odds ratio for estimated responder rate on weekly mean 24-hour average pain NRS in week 4 between BAY2395840 and placebo among subjects achieving $\geq 50\%$ improvement in pain compared to baseline

| | |
|-------------------|--|
| Comparison groups | Dosage A of BAY2395840 in PPS v Placebo in PPS |
|-------------------|--|

| | |
|---|-----------------------|
| Number of subjects included in analysis | 156 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[14] |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.653 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 0.2681 |
| upper limit | 1.5904 |

Notes:

[14] - Database auto-calculates total number of subjects erroneously, analysed number of subjects was 78.

| | |
|-----------------------------------|-----------------------------------|
| Statistical analysis title | Marginal responder rates analysis |
|-----------------------------------|-----------------------------------|

Statistical analysis description:

Odds ratio for estimated responder rate on weekly mean 24-hour average pain NRS in week 4 between BAY2395840 and placebo among subjects achieving $\geq 30\%$ improvement in pain compared to baseline

| | |
|---|--|
| Comparison groups | Dosage A of BAY2395840 in PPS v Placebo in PPS |
| Number of subjects included in analysis | 156 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[15] |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.5143 |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 0.2624 |
| upper limit | 1.008 |

Notes:

[15] - Database auto-calculates total number of subjects erroneously, analysed number of subjects was 78.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs started or worsened after application of study intervention and up to 14 days after the last study intervention per period

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 25.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------------|
| Reporting group title | Placebo in SAF |
|-----------------------|----------------|

Reporting group description:

Subjects treated with matching placebo in the SAF. Overall, 80 participants were valid for SAF. 2 participants (1 in Group 1 with BAY2395840 - placebo treatment sequence, 1 in Group 2 with placebo - BAY2395840 treatment sequence) did not enter period 2. Thus, 79 participants were treated with placebo in the SAF.

| | |
|-----------------------|-------------------------------|
| Reporting group title | Dosage A of BAY2395840 in SAF |
|-----------------------|-------------------------------|

Reporting group description:

Subjects treated with BAY2395840 in the SAF. Overall, 80 participants were valid for SAF. 2 participants (1 in Group 1 with BAY2395840 - placebo treatment sequence, 1 in Group 2 with placebo - BAY2395840 treatment sequence) did not enter period 2. Thus, 79 participants were treated with BAY2395840 in the SAF.

| Serious adverse events | Placebo in SAF | Dosage A of BAY2395840 in SAF | |
|---|----------------|-------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 79 (2.53%) | 2 / 79 (2.53%) | |
| number of deaths (all causes) | 1 | 1 | |
| number of deaths resulting from adverse events | 1 | 0 | |
| Psychiatric disorders | | | |
| Anxiety disorder | | | |
| subjects affected / exposed | 0 / 79 (0.00%) | 1 / 79 (1.27%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 79 (1.27%) | 0 / 79 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 1 / 79 (1.27%) | 1 / 79 (1.27%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Placebo in SAF | Dosage A of BAY2395840 in SAF | |
|---|----------------|-------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 79 (8.86%) | 11 / 79 (13.92%) | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 6 / 79 (7.59%) | 5 / 79 (6.33%) | |
| occurrences (all) | 14 | 5 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 79 (0.00%) | 4 / 79 (5.06%) | |
| occurrences (all) | 0 | 4 | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 1 / 79 (1.27%) | 4 / 79 (5.06%) | |
| occurrences (all) | 1 | 4 | |

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