



Clinical trial results:

A Double-Blind, Randomised, Placebo Controlled, Adaptive Design Study of the Efficacy, Safety and Pharmacokinetics of NT-814 in Female Subjects With Moderate to Severe Vasomotor Symptoms Associated With the Menopause

Summary

EudraCT number	2018-002763-26
Trial protocol	GB
Global end of trial date	21 November 2019

Results information

Result version number	v2 (current)
This version publication date	16 June 2023
First version publication date	05 December 2020
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	BAY3427080/21686
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03596762
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser Wilhelm Allee, Leverkusen, Germany,
Public contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, 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 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objectives: - To evaluate the efficacy of once daily doses of 40 mg, 80 mg, 120 mg and 160 mg BAY3427080 (NT-814), compared with placebo, in reducing the frequency and severity of hot flashes. - To assess the safety and tolerability of once daily doses of 40 mg, 80 mg, 120 mg and 160 mg BAY3427080 (NT-814), compared with placebo, in subjects with post-menopausal symptoms.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the International Conference on Harmonization guideline E6: Good Clinical Practice. Only after the subject voluntarily signed the informed consent form was he/she able to enter the study. If the subject was not capable of providing a signature, an oral statement of consent could have been given in the presence of a witness. Each subject was assured of the right to 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	19 November 2018
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	Canada: 33
Country: Number of subjects enrolled	United Kingdom: 95
Country: Number of subjects enrolled	United States: 71
Worldwide total number of subjects	199
EEA total number of subjects	0

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)	198
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted between 20 November 2018 (first subject, first visit) and 21 November 2019 (last subject, last visit) at 11 sites in the USA, nine sites in the UK, and five sites in Canada.

Pre-assignment

Screening details:

A total of 760 subjects were screened, of whom 199 completed screening and were randomised. Not meeting the eligibility criteria was the reason provided for all screening failures (561). A total of 47 subjects were randomised to placebo and 152 subjects to Elinzanetant (BAY3427080).

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	Placebo

Arm description:

Subjects received four placebo capsules orally once daily in the evening before bedtime.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

4 x placebo capsules

Arm title	40 mg Elinzanetant (BAY3427080)
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Arm description:

Subjects received one 40 mg elinzanetant capsule and 3 placebo capsules.

Arm type	Experimental
Investigational medicinal product name	Elinzanetant
Investigational medicinal product code	BAY3427080
Other name	NT-814
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

one capsule of 40 mg elinzanetant once daily in the evening before bedtime.

Arm title	80 mg Elinzanetant (BAY3427080)
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Arm description:

subjects received 2x40 mg elinzanetant capsules and 2 placebo capsules.

Arm type	Experimental
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Investigational medicinal product name	Elinzanetant
Investigational medicinal product code	BAY3427080
Other name	NT-814
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Two capsules of 40 mg elinzanetant once daily in the evening before bedtime.

Arm title	120 mg Elinzanetant (BAY3427080)
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Arm description:

Subjects received 3x40 mg elinzanetant capsules and 1 placebo capsule.

Arm type	Experimental
Investigational medicinal product name	Elinzanetant
Investigational medicinal product code	BAY3427080
Other name	NT-814
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Three capsules of 40 mg elinzanetant once daily in the evening before bedtime.

Arm title	160 mg Elinzanetant (BAY3427080)
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Arm description:

Subjects received 4x40 mg elinzanetant capsules.

Arm type	Experimental
Investigational medicinal product name	Elinzanetant
Investigational medicinal product code	BAY3427080
Other name	NT-814
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Four capsules of 40 mg elinzanetant once daily in the evening before bedtime.

Number of subjects in period 1	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)
Started	47	31	17
Completed	43	30	16
Not completed	4	1	1
Consent withdrawn by subject	2	1	-
Adverse event, non-fatal	2	-	1
Protocol deviation	-	-	-

Number of subjects in period 1	120 mg Elinzanetant (BAY3427080)	160 mg Elinzanetant (BAY3427080)
Started	52	52
Completed	51	45
Not completed	1	7
Consent withdrawn by subject	1	1
Adverse event, non-fatal	-	5
Protocol deviation	-	1

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received four placebo capsules orally once daily in the evening before bedtime.	
Reporting group title	40 mg Elinzanetant (BAY3427080)
Reporting group description: Subjects received one 40 mg elinzanetant capsule and 3 placebo capsules.	
Reporting group title	80 mg Elinzanetant (BAY3427080)
Reporting group description: subjects received 2x40 mg elinzanetant capsules and 2 placebo capsules.	
Reporting group title	120 mg Elinzanetant (BAY3427080)
Reporting group description: Subjects received 3x40 mg elinzanetant capsules and 1 placebo capsule.	
Reporting group title	160 mg Elinzanetant (BAY3427080)
Reporting group description: Subjects received 4x40 mg elinzanetant capsules.	

Reporting group values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)
Number of subjects	47	31	17
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	55.6	55.4	55.9
standard deviation	± 4.1	± 4.0	± 4.2
Gender Categorical Units: Subjects			
Female	47	31	17
Male	0	0	0
Race Units: Subjects			
Asian	2	0	0
Black or African American	6	5	3
White	38	24	13
Other	1	2	1
Ethnicity			

Units: Subjects			
Hispanic or Latino	2	2	1
Not Hispanic or Latino	45	29	16

Reporting group values	120 mg Elinzanetant (BAY3427080)	160 mg Elinzanetant (BAY3427080)	Total
Number of subjects	52	52	199
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	54.8	55.0	-
standard deviation	± 4.4	± 3.8	
Gender Categorical Units: Subjects			
Female	52	52	199
Male	0	0	0
Race Units: Subjects			
Asian	1	1	4
Black or African American	13	11	38
White	37	40	152
Other	1	0	5
Ethnicity Units: Subjects			
Hispanic or Latino	2	6	13
Not Hispanic or Latino	50	46	186

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received four placebo capsules orally once daily in the evening before bedtime.	
Reporting group title	40 mg Elinzanetant (BAY3427080)
Reporting group description: Subjects received one 40 mg elinzanetant capsule and 3 placebo capsules.	
Reporting group title	80 mg Elinzanetant (BAY3427080)
Reporting group description: subjects received 2x40 mg elinzanetant capsules and 2 placebo capsules.	
Reporting group title	120 mg Elinzanetant (BAY3427080)
Reporting group description: Subjects received 3x40 mg elinzanetant capsules and 1 placebo capsule.	
Reporting group title	160 mg Elinzanetant (BAY3427080)
Reporting group description: Subjects received 4x40 mg elinzanetant capsules.	
Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis
Subject analysis set description: All subjects who received at least one dose of double-blind study drug, irrespective of treatment received. Subjects were analysed according to treatment received.	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description: All randomised subjects who received at least one dose of double-blind study drug, irrespective of treatment received, and had hot flush data for at least 7 days' worth of post-treatment assessments (i.e. requirement for primary efficacy endpoint). Subjects were analysed according to randomised treatment.	
Subject analysis set title	Per Protocol (PP) Set
Subject analysis set type	Per protocol
Subject analysis set description: All subjects in the FAS who completed the 12-week treatment period excluding those identified as having relevant protocol deviations.	

Primary: Mean change from baseline in mean daily frequency of moderate and severe hot flushes from baseline to Week 4

End point title	Mean change from baseline in mean daily frequency of moderate and severe hot flushes from baseline to Week 4
End point description: Subjects recorded daily in their electronic diary (eDiary) the frequency and severity of hot flushes during the treatment period. The baseline assessment for hot flushes was calculated using the last 7 days (not necessarily consecutive days) with an available data in the evening and/or the morning of the baseline diary completion period. A diary day was comprised of the evening entry of this day and the morning entry of the following day, in that order. Mean daily frequency = Sum of number of hot flushes filled in the diary during the last 7 diary days (with at least one available data in the evening and/or morning) divided by 7. Moderate: Sensation of heat with sweating, but able to continue activity. Severe: Sensation of heat with sweating, causing cessation (stopping) of activity. In categories the number of subjects analyzed (N) at week 4 is mentioned for each reporting group respectively.	
End point type	Primary
End point timeframe: From baseline to week 4	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Hot Flushes per day				
arithmetic mean (standard deviation)				
Baseline	11.82 (± 4.42)	12.13 (± 8.81)	14.55 (± 5.87)	13.54 (± 7.17)
Week 4: Change from baseline (N=45,31,17,52,47)	-2.45 (± 3.65)	-4.19 (± 5.78)	-4.30 (± 6.45)	-6.76 (± 5.85)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Hot Flushes per day				
arithmetic mean (standard deviation)				
Baseline	12.92 (± 6.90)			
Week 4: Change from baseline (N=45,31,17,52,47)	-5.42 (± 5.36)			

Statistical analyses

Statistical analysis title	40 mg BAY3427080 versus placebo
Comparison groups	Placebo v 40 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1946
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.83
upper limit	0.78

Statistical analysis title	80 mg BAY3427080 versus placebo
Comparison groups	Placebo v 80 mg Elinzanetant (BAY3427080)

Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3682
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.11
upper limit	1.53

Statistical analysis title	120 mg BAY3427080 versus placebo
Comparison groups	Placebo v 120 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-3.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.94
upper limit	-1.92

Statistical analysis title	160 mg BAY3427080 versus placebo
Comparison groups	Placebo v 160 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0115
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-2.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.66
upper limit	-0.6

Primary: Mean change from baseline in mean daily frequency of moderate and

severe hot flushes from baseline to Week 12

End point title	Mean change from baseline in mean daily frequency of moderate and severe hot flushes from baseline to Week 12
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End point description:

Subjects recorded daily in their electronic diary (eDiary) the frequency and severity of hot flushes during the treatment period. The baseline assessment for hot flushes was calculated using the last 7 days (not necessarily consecutive days) with an available data in the evening and/or the morning of the baseline diary completion period. A diary day was comprised of the evening entry of this day and the morning entry of the following day, in that order. Mean daily frequency = Sum of number of hot flushes filled in the diary during the last 7 diary days (with at least one available data in the evening and/or morning) divided by 7. Moderate: Sensation of heat with sweating, but able to continue activity. Severe: Sensation of heat with sweating, causing cessation (stopping) of activity. In categories the number of subjects analyzed (N) at week 12 is mentioned for each reporting group respectively.

End point type	Primary
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End point timeframe:

Week 12

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	11.82 (± 4.42)	12.13 (± 8.81)	14.55 (± 5.87)	13.54 (± 7.17)
Week 12: Change from baseline (N=44,30,16,51,43)	-4.49 (± 4.29)	-6.48 (± 7.82)	-5.49 (± 5.31)	-7.91 (± 6.66)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	12.92 (± 6.90)			
Week 12: Change from baseline (N=44,30,16,51,43)	-6.57 (± 5.83)			

Statistical analyses

Statistical analysis title	40 mg BAY3427080 versus placebo
Comparison groups	Placebo v 40 mg Elinzanetant (BAY3427080)

Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2097
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-1.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.28
upper limit	-0.95

Statistical analysis title	120 mg BAY3427080 versus placebo
Comparison groups	Placebo v 120 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0116
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-2.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.22
upper limit	-0.67

Statistical analysis title	160 mg BAY3427080 versus placebo
Comparison groups	Placebo v 160 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1346
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-1.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.12
upper limit	0.56

Statistical analysis title	80 mg BAY3427080 versus placebo
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Comparison groups	Placebo v 80 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6369
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.97
upper limit	2.44

Primary: Mean change from baseline in mean severity of moderate and severe hot flushes from baseline to Week 4

End point title	Mean change from baseline in mean severity of moderate and severe hot flushes from baseline to Week 4
End point description:	Subjects recorded daily in their eDiary the frequency and severity of hot flushes during the treatment period. Mean weekly severity = (number of moderate hot flushes for 7 days) x 2 + (number of severe hot flushes for 7 days) x 3] / (total number of moderate to severe hot flushes over 7 days). Severity is graded by the women from 1 to 3 (1 = mild; 2 = moderate; 3 = severe). In categories the number of subjects analyzed (N) at week 4 is mentioned for each reporting group respectively.
End point type	Primary
End point timeframe:	
From baseline to week 4	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	2.54 (± 0.20)	2.51 (± 0.26)	2.63 (± 0.24)	2.54 (± 0.24)
Week 4: Change from baseline (N=45,31,17,50,45)	-0.31 (± 0.41)	-0.38 (± 0.54)	-0.44 (± 0.56)	-0.51 (± 0.57)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	2.54 (± 0.26)			

Week 4: Change from baseline (N=45,31,17,50,45)	-0.54 (\pm 0.67)			
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Statistical analyses

Statistical analysis title	40 mg BAY3427080 versus placebo
Comparison groups	Placebo v 40 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7033
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.2

Statistical analysis title	160 mg BAY3427080 versus placebo
Comparison groups	Placebo v 160 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.09
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	0.03

Statistical analysis title	120 mg BAY3427080 versus placebo
Comparison groups	Placebo v 120 mg Elinzanetant (BAY3427080)

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0896
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	0.03

Statistical analysis title	80 mg BAY3427080 versus placebo
Comparison groups	Placebo v 80 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3724
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	0.17

Primary: Mean change from baseline in mean severity of moderate and severe hot flushes from baseline to Week 12

End point title	Mean change from baseline in mean severity of moderate and severe hot flushes from baseline to Week 12
End point description: Subjects recorded daily in their eDiary the frequency and severity of hot flushes during the treatment period. Mean weekly severity = (number of moderate hot flushes for 7 days) x 2 + (number of severe hot flushes for 7 days) x 3] / (total number of moderate to severe hot flushes over 7 days). Severity was graded by the women from 1 to 3 (1 = mild; 2 = moderate; 3 = severe). In categories the number of subjects analyzed (N) at week 12 is mentioned for each reporting group respectively.	
End point type	Primary
End point timeframe: Week 12	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	2.54 (± 0.20)	2.51 (± 0.26)	2.63 (± 0.24)	2.54 (± 0.24)
Week 12: Change from baseline (N=44,30,16,49,41)	-0.41 (± 0.50)	-0.53 (± 0.64)	-0.26 (± 0.45)	-0.56 (± 0.68)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	2.54 (± 0.26)			
Week 12: Change from baseline (N=44,30,16,49,41)	-0.73 (± 0.78)			

Statistical analyses

Statistical analysis title	40 mg BAY3427080 versus placebo
Comparison groups	Placebo v 40 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5511
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.39
upper limit	0.21

Statistical analysis title	160 mg BAY3427080 versus placebo
Comparison groups	Placebo v 160 mg Elinzanetant (BAY3427080)

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0479
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	0

Statistical analysis title	120 mg BAY3427080 versus placebo
Comparison groups	Placebo v 120 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2606
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	0.11

Statistical analysis title	80 mg BAY3427080 versus placebo
Comparison groups	Placebo v 80 mg Elinzanetant (BAY3427080)
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3822
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference in LS means
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.52

Secondary: Mean change from baseline in frequency of mean daily moderate and

severe hot flushes from baseline to Weeks 1, 2, 8 and 16

End point title	Mean change from baseline in frequency of mean daily moderate and severe hot flushes from baseline to Weeks 1, 2, 8 and 16
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End point description:

Subjects recorded daily in their electronic diary (eDiary) the frequency and severity of hot flushes during the treatment period. The baseline assessment for hot flushes was calculated using the last 7 days (not necessarily consecutive days) with an available data in the evening and/or the morning of the baseline diary completion period. A diary day was comprised of the evening entry of this day and the morning entry of the following day, in that order. Mean daily frequency = Sum of number of hot flushes filled in the diary during the last 7 diary days (with at least one available data in the evening and/or morning) divided by 7. Moderate: Sensation of heat with sweating, but able to continue activity. Severe: Sensation of heat with sweating, causing cessation (stopping) of activity In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 1, 2, 8 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	11.82 (± 4.42)	12.13 (± 8.81)	14.55 (± 5.87)	13.54 (± 7.17)
Week 1: Change from baseline (N=47,31,17,52,52)	-1.22 (± 3.07)	-1.61 (± 3.05)	-1.63 (± 3.56)	-3.22 (± 3.43)
Week 2: Change from baseline (N=45,31,17,52,51)	-2.19 (± 4.01)	-3.03 (± 3.95)	-3.47 (± 4.37)	-4.58 (± 4.70)
Week 8: Change from baseline (N=44,31,17,51,44)	-4.33 (± 4.79)	-5.72 (± 6.18)	-5.94 (± 5.26)	-7.84 (± 5.95)
Week 16: Change from baseline (N=43,30,16,51,42)	-3.95 (± 4.85)	-5.74 (± 9.45)	-2.01 (± 4.99)	-5.95 (± 6.95)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	12.92 (± 6.90)			
Week 1: Change from baseline (N=47,31,17,52,52)	-3.09 (± 3.76)			
Week 2: Change from baseline (N=45,31,17,52,51)	-3.78 (± 4.48)			
Week 8: Change from baseline (N=44,31,17,51,44)	-5.58 (± 6.00)			
Week 16: Change from baseline (N=43,30,16,51,42)	-2.78 (± 6.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in mean severity of moderate and severe hot flushes from baseline to Weeks 1, 2, 8 and 16

End point title	Mean change from baseline in mean severity of moderate and severe hot flushes from baseline to Weeks 1, 2, 8 and 16
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End point description:

Subjects recorded daily in their diary the frequency and severity of hot flushes during the treatment period. Mean weekly severity = (number of moderate hot flushes for 7 days) x 2 + (number of severe hot flushes for 7 days) x 3] / (total number of moderate to severe hot flushes over 7 days). Severity is graded by the women from 1 to 3 (1 = mild; 2 = moderate; 3 = severe). In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 1, 2, 8 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	50
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,50,50)	2.54 (± 0.20)	2.51 (± 0.26)	2.63 (± 0.24)	2.54 (± 0.24)
Week 1: Change from baseline (N=47,31,17,50,50)	-0.24 (± 0.30)	-0.21 (± 0.20)	-0.22 (± 0.21)	-0.25 (± 0.28)
Week 2: Change from baseline (N=45,31,17,50,49)	-0.30 (± 0.39)	-0.32 (± 0.32)	-0.42 (± 0.58)	-0.37 (± 0.46)
Week 8: Change from baseline (N=44,31,17,50,42)	-0.45 (± 0.58)	-0.48 (± 0.54)	-0.40 (± 0.61)	-0.51 (± 0.54)
Week 16: Change from baseline (N=43,30,16,49,41)	2.15 (± 0.65)	2.03 (± 0.56)	2.50 (± 0.46)	2.13 (± 0.71)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,50,50)	2.55 (± 0.26)			

Week 1: Change from baseline (N=47,31,17,50,50)	-0.26 (± 0.26)			
Week 2: Change from baseline (N=45,31,17,50,49)	-0.40 (± 0.55)			
Week 8: Change from baseline (N=44,31,17,50,42)	-0.65 (± 0.73)			
Week 16: Change from baseline (N=43,30,16,49,41)	2.08 (± 0.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in mean daily frequency of all hot flushes from baseline to Weeks 1, 2, 4, 8, 12 and 16

End point title	Mean change from baseline in mean daily frequency of all hot flushes from baseline to Weeks 1, 2, 4, 8, 12 and 16
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End point description:

Subjects recorded daily in their electronic diary (eDiary) the frequency and severity of hot flushes during the treatment period. The baseline assessment for hot flushes was calculated using the last 7 days (not necessarily consecutive days) with an available data in the evening and/or the morning of the baseline diary completion period. A diary day was comprised of the evening entry of this day and the morning entry of the following day, in that order. Mean daily frequency = Sum of number of hot flushes filled in the diary during the last 7 diary days (with at least one available data in the evening and/or morning) divided by 7. Moderate: Sensation of heat with sweating, but able to continue activity. Severe: Sensation of heat with sweating, causing cessation (stopping) of activity. *In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 1, 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	14.04 (± 5.57)	14.19 (± 11.01)	16.55 (± 6.89)	15.39 (± 7.91)
Week 1 (N=47,31,17,52,52)	-1.36 (± 3.03)	-1.72 (± 3.27)	-1.33 (± 5.68)	-3.30 (± 3.99)
Week 2 (N=45,31,17,52,51)	-2.35 (± 4.60)	-2.99 (± 4.90)	-2.74 (± 5.97)	-4.57 (± 5.48)
Week 4 (N=45,31,17,52,47)	-2.67 (± 4.09)	-4.11 (± 6.31)	-3.45 (± 8.54)	-6.70 (± 6.16)
Week 8 (N=44,31,17,51,44)	-4.74 (± 5.57)	-5.65 (± 6.55)	-5.45 (± 6.56)	-7.96 (± 6.16)
Week 12 (N=44,30,16,51,43)	-5.07 (± 5.48)	-6.50 (± 8.67)	-5.11 (± 8.41)	-7.94 (± 6.74)
Week 16 (N=43,30,16,51,42)	-4.60 (± 6.17)	-5.83 (± 10.86)	-1.76 (± 7.50)	-6.19 (± 7.68)

End point values	160 mg			
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Elinzanetant (BAY3427080)				
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	15.78 (± 9.62)			
Week 1 (N=47,31,17,52,52)	-3.69 (± 4.81)			
Week 2 (N=45,31,17,52,51)	-4.43 (± 5.68)			
Week 4 (N=45,31,17,52,47)	-5.79 (± 6.09)			
Week 8 (N=44,31,17,51,44)	-6.03 (± 6.43)			
Week 12 (N=44,30,16,51,43)	-7.47 (± 7.13)			
Week 16 (N=43,30,16,51,42)	-3.11 (± 6.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in mean severity of all hot flushes from baseline to Weeks 1, 2, 4, 8, 12 and 16

End point title	Mean change from baseline in mean severity of all hot flushes from baseline to Weeks 1, 2, 4, 8, 12 and 16
End point description:	
Subjects recorded daily in their diary the frequency and severity of hot flushes during the treatment period. Mean weekly severity = (number of moderate hot flushes for 7 days) x 2 + (number of severe hot flushes for 7 days) x 3] / (total number of moderate to severe hot flushes over 7 days). Severity is graded by the women from 1 to 3 (1 = mild; 2 = moderate; 3 = severe). In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.	
End point type	Secondary
End point timeframe:	
From baseline to Weeks 1, 2, 4, 8, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	2.34 (± 0.32)	2.34 (± 0.35)	2.46 (± 0.37)	2.38 (± 0.34)
Week 1: Change from baseline (N=47,31,17,52,52)	-0.04 (± 0.23)	-0.04 (± 0.18)	-0.05 (± 0.12)	-0.09 (± 0.25)
Week 2: Change from baseline (N=45,31,17,52,51)	-0.10 (± 0.32)	-0.15 (± 0.27)	-0.25 (± 0.52)	-0.21 (± 0.46)
Week 4: Change from baseline (N=45,31,17,52,47)	-0.11 (± 0.36)	-0.21 (± 0.47)	-0.27 (± 0.49)	-0.35 (± 0.60)
Week 8: Change from baseline (N=44,31,17,51,44)	-0.25 (± 0.54)	-0.31 (± 0.47)	-0.23 (± 0.52)	-0.35 (± 0.55)
Week 12: Change from baseline (N=44,30,16,51,43)	-0.21 (± 0.44)	-0.35 (± 0.57)	-0.08 (± 0.41)	-0.41 (± 0.62)

Week 16: Change from baseline (N=43,30,16,51,42)	-0.21 (± 0.49)	-0.30 (± 0.52)	0.05 (± 0.34)	-0.26 (± 0.56)
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End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Hot Flushes				
arithmetic mean (standard deviation)				
Baseline	2.35 (± 0.39)			
Week 1: Change from baseline (N=47,31,17,52,52)	-0.07 (± 0.18)			
Week 2: Change from baseline (N=45,31,17,52,51)	-0.20 (± 0.50)			
Week 4: Change from baseline (N=45,31,17,52,47)	-0.34 (± 0.63)			
Week 8: Change from baseline (N=44,31,17,51,44)	-0.44 (± 0.72)			
Week 12: Change from baseline (N=44,30,16,51,43)	-0.52 (± 0.79)			
Week 16: Change from baseline (N=43,30,16,51,42)	-0.24 (± 0.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in the mean daily hot flush score (frequency x severity) at Weeks 1, 2, 4, 8, 12 and 16

End point title	Mean change from baseline in the mean daily hot flush score (frequency x severity) at Weeks 1, 2, 4, 8, 12 and 16
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End point description:

Mean daily Hot Flushes score = Sum of (frequency x severity) filled in the diary during the last 7 days (with at least one available data in the evening and/or morning) divided by 7. Severity is graded by the women from 1 to 3 (1 = mild; 2 = moderate; 3 = severe). In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 1, 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Scores on scale				
arithmetic mean (standard deviation)				

Baseline (N=47,31,17,52,52)	32.35 (± 12.24)	32.84 (± 24.82)	40.76 (± 17.08)	36.59 (± 19.88)
Week 1: Change from baseline (N=47,31,17,52,52)	-3.09 (± 8.16)	-4.26 (± 7.93)	-4.18 (± 11.27)	-8.44 (± 8.98)
Week 2: Change from baseline (N=45,31,17,52,51)	-5.62 (± 11.00)	-7.88 (± 10.77)	-9.08 (± 13.09)	-11.98 (± 12.39)
Week 4: Change from baseline (N=45,31,17,52,47)	-6.62 (± 9.79)	-10.68 (± 15.26)	-11.39 (± 18.82)	-17.54 (± 15.50)
Week 8: Change from baseline (N=44,31,17,51,44)	-11.63 (± 12.51)	-14.64 (± 16.33)	-16.17 (± 15.32)	-20.54 (± 15.80)
Week 12: Change from baseline (N=44,30,16,51,43)	-12.33 (± 11.96)	-16.71 (± 20.60)	-14.93 (± 16.83)	-20.72 (± 17.81)
Week 16: Change from baseline (N=43,30,16,51,42)	-10.89 (± 13.45)	-14.93 (± 25.48)	-4.97 (± 14.35)	-15.60 (± 19.03)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	35.73 (± 19.75)			
Week 1: Change from baseline (N=47,31,17,52,52)	-8.67 (± 10.53)			
Week 2: Change from baseline (N=45,31,17,52,51)	-10.51 (± 12.47)			
Week 4: Change from baseline (N=45,31,17,52,47)	-14.20 (± 14.30)			
Week 8: Change from baseline (N=44,31,17,51,44)	-14.89 (± 15.36)			
Week 12: Change from baseline (N=44,30,16,51,43)	-17.70 (± 15.38)			
Week 16: Change from baseline (N=43,30,16,51,42)	-7.50 (± 16.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with ≥50% and ≥80% reduction from baseline in mean daily hot flushes frequency at Week 12

End point title	Number of subjects with ≥50% and ≥80% reduction from baseline in mean daily hot flushes frequency at Week 12
End point description:	Proportion of responder is number of subjects with >=50 (80)% reduction from baseline in the number of moderate and severe hot flushes.
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	30	16	51
Units: Subjects				
>= 50% reduction	17	20	5	32
>=80% reduction	8	6	0	16

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: Subjects				
>= 50% reduction	30			
>=80% reduction	18			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in number of all night-time awakenings (NTA) at Weeks 1, 2, 4, 8, 12 and 16

End point title	Mean change from baseline in number of all night-time awakenings (NTA) at Weeks 1, 2, 4, 8, 12 and 16
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End point description:

Subjects were provided with an eDiary to document the number of night-time awakenings (NTA). Each evening, subjects recorded the total number of hot flushes of each severity experienced that day since waking. Each morning upon waking, subjects recorded the number of times they woke up in the night and the total number of hot flushes of each severity experienced during the night. In categories the number of subjects analyzed (N) at each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to weeks 1, 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Night-time awakenings				
arithmetic mean (standard deviation)				

Baseline	3.86 (± 2.06)	3.44 (± 1.82)	5.00 (± 1.76)	3.80 (± 2.20)
Week 1: Change from baseline (N=47,31,17,52,52)	-0.65 (± 1.08)	-0.70 (± 1.24)	-0.57 (± 1.57)	-0.91 (± 1.06)
Week 2: Change from baseline (N=47,31,17,52,51)	-0.62 (± 1.54)	-0.70 (± 1.20)	-1.09 (± 1.84)	-1.10 (± 1.34)
Week 4: Change from baseline (N=45,31,17,52, 47)	-0.86 (± 1.40)	-1.05 (± 1.43)	-0.99 (± 2.96)	-1.49 (± 1.43)
Week 8: Change from baseline (N=44,31,17,51,44)	-0.99 (± 1.31)	-1.66 (± 1.77)	-1.30 (± 2.15)	-1.79 (± 1.47)
Week 12: Change from baseline (N=44,30,16,51,43)	-1.28 (± 1.44)	-1.53 (± 1.89)	-1.61 (± 2.46)	-1.60 (± 1.38)
Week 16: Change from baseline (N=43,30,16,51,42)	-1.08 (± 1.30)	-0.96 (± 1.91)	-0.31 (± 2.90)	-1.05 (± 1.30)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Night-time awakenings				
arithmetic mean (standard deviation)				
Baseline	3.85 (± 2.57)			
Week 1: Change from baseline (N=47,31,17,52,52)	-0.86 (± 1.93)			
Week 2: Change from baseline (N=47,31,17,52,51)	-1.00 (± 2.10)			
Week 4: Change from baseline (N=45,31,17,52, 47)	-1.03 (± 2.22)			
Week 8: Change from baseline (N=44,31,17,51,44)	-1.17 (± 2.51)			
Week 12: Change from baseline (N=44,30,16,51,43)	-1.40 (± 2.40)			
Week 16: Change from baseline (N=43,30,16,51,42)	-0.32 (± 2.10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in mean daily number of NTAs secondary to hot flushes at Weeks 1, 2, 4, 8, 12 and 16

End point title	Mean change from baseline in mean daily number of NTAs secondary to hot flushes at Weeks 1, 2, 4, 8, 12 and 16
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End point description:

Subjects were provided with an eDiary to document the number of night-time awakenings (NTA). Each evening, subjects recorded the total number of hot flashes of each severity experienced that day since waking. Each morning upon waking, subjects recorded the number of times they woke up in the night and the total number of hot flashes of each severity experienced during the night. Night-time awakenings secondary to hot flashes corresponded to severe hot flash recorded on the morning diary, and all NTAs corresponded to the data recorded in the "Total number of times you woke up last night?" field from the eDiary recorded in the morning. Number of NTAs secondary to hot flushes could not be higher than the number of all NTAs.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 1, 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Night-time awakenings				
arithmetic mean (standard deviation)				
Baseline	2.90 (± 1.64)	2.41 (± 1.57)	4.05 (± 1.86)	2.76 (± 1.71)
Week 1: Change from baseline (N=47,31,17,52,52)	-0.57 (± 0.96)	-0.52 (± 1.07)	-0.63 (± 1.53)	-0.90 (± 1.03)
Week 2: Change from baseline (N=45,31,17,52,51)	-0.69 (± 1.03)	-0.75 (± 1.18)	-1.13 (± 1.89)	-1.18 (± 1.27)
Week 4: Change from baseline (N=45,31,17,52,47)	-0.89 (± 1.08)	-0.91 (± 1.26)	-1.33 (± 2.27)	-1.53 (± 1.19)
Week 8: Change from baseline (N=44,31,17,51,44)	-1.09 (± 1.36)	-1.50 (± 1.40)	-1.69 (± 2.21)	-1.79 (± 1.35)
Week 12: Change from baseline (N=44,30,16,51,43)	-1.31 (± 1.39)	-1.63 (± 1.46)	-1.70 (± 2.53)	-1.67 (± 1.27)
Week 16: Change from baseline (N=43,30,16,51,42)	-1.05 (± 1.19)	-1.29 (± 1.63)	-0.45 (± 2.05)	-1.19 (± 1.23)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Night-time awakenings				
arithmetic mean (standard deviation)				
Baseline	2.57 (± 1.54)			
Week 1: Change from baseline (N=47,31,17,52,52)	-0.68 (± 1.14)			
Week 2: Change from baseline (N=45,31,17,52,51)	-0.92 (± 1.38)			
Week 4: Change from baseline (N=45,31,17,52,47)	-1.01 (± 1.62)			
Week 8: Change from baseline (N=44,31,17,51,44)	-1.13 (± 1.86)			
Week 12: Change from baseline (N=44,30,16,51,43)	-1.32 (± 1.75)			
Week 16: Change from baseline (N=43,30,16,51,42)	-0.44 (± 1.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the global and individual domain scores of the Pittsburgh Sleep Quality Index (PSQI) at Weeks 4, 8, 12 and 16

End point title	Change from baseline in the global and individual domain scores of the Pittsburgh Sleep Quality Index (PSQI) at Weeks 4, 8, 12 and 16
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End point description:

The PSQI is a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. Nineteen individual items generate seven "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these seven components yields one global score. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=45,31,17,51,50)	10.80 (± 2.39)	11.94 (± 3.11)	11.35 (± 3.66)	10.80 (± 3.00)
Week 4: Change from baseline (N=41,31,17,50,45)	-0.63 (± 2.02)	-1.87 (± 2.93)	-1.94 (± 2.68)	-2.70 (± 3.11)
Week 8: Change from baseline (N=42,31,16,51,43)	-1.36 (± 2.90)	-2.39 (± 3.63)	-2.38 (± 3.30)	-3.00 (± 3.23)
Week 12: Change from baseline (N=41,30,16,49,41)	-1.15 (± 2.95)	-2.47 (± 3.82)	-2.81 (± 2.97)	-3.39 (± 3.12)
Week 16: Change from baseline (N=41,30,16,50,42)	-1.85 (± 2.46)	-2.10 (± 3.53)	-1.38 (± 3.26)	-2.24 (± 3.12)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=45,31,17,51,50)	11.44 (± 3.14)			
Week 4: Change from baseline (N=41,31,17,50,45)	-2.80 (± 2.84)			
Week 8: Change from baseline (N=42,31,16,51,43)	-3.14 (± 3.37)			
Week 12: Change from baseline (N=41,30,16,49,41)	-3.54 (± 4.12)			
Week 16: Change from baseline (N=41,30,16,50,42)	-1.79 (± 2.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the Insomnia Severity Index (ISI) score at Weeks 4, 8, 12 and 16

End point title	Change from baseline in the Insomnia Severity Index (ISI) score at Weeks 4, 8, 12 and 16
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End point description:

The ISI is a brief self-report questionnaire assessing the nature, severity, and impact of insomnia. The ISI comprises seven items assessing the perceived severity of difficulties initiating sleep, staying asleep, and early morning awakenings, satisfaction with current sleep pattern, interference with daily functioning, noticeability of impairment attributed to the sleep problem, and degree of distress or concern caused by the sleep problem. Subjects rated each item on a scale of 0 to 4, yielding a total score ranging from 0 to 28. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=44,31,17,51,50)	12.43 (± 5.09)	13.23 (± 5.36)	13.24 (± 8.04)	12.63 (± 5.66)
Week 4: Change from Baseline (N=40,31,17,50,45)	-1.60 (± 2.98)	-2.74 (± 4.91)	-3.65 (± 6.03)	-5.14 (± 5.51)
Week 8: Change from Baseline (N=41,31,16,51,43)	-1.51 (± 3.64)	-3.74 (± 5.63)	-4.44 (± 6.17)	-6.20 (± 4.93)
Week 12: Change from Baseline (N=40,30,16, 49,41)	-1.95 (± 4.70)	-3.80 (± 5.45)	-5.81 (± 5.86)	-6.12 (± 5.41)
Week 16: Change from Baseline (N=40,30,16,50,42)	-2.65 (± 4.32)	-3.73 (± 6.02)	-3.00 (± 3.72)	-4.34 (± 5.58)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Scores on scale				
arithmetic mean (standard deviation)				

Baseline (N=44,31,17,51,50)	13.74 (± 5.89)			
Week 4: Change from Baseline (N=40,31,17,50,45)	-5.42 (± 5.42)			
Week 8: Change from Baseline (N=41,31,16,51,43)	-5.72 (± 5.14)			
Week 12: Change from Baseline (N=40,30,16, 49,41)	-7.39 (± 5.82)			
Week 16: Change from Baseline (N=40,30,16,50,42)	-4.00 (± 5.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the hot flush related daily interference scale (HFRDIS) scores at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in the hot flush related daily interference scale (HFRDIS) scores at Weeks 2, 4, 8, 12 and 16
End point description:	
The HFRDIS is a 10-item, self-report questionnaire assessing the impact of hot flashes on a woman's life during the past week. For each of the 10 items, subjects rated how much hot flushes had interfered with that aspect of their life on a scale of 0 (not at all) to 10 (very much so). In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.	
End point type	Secondary
End point timeframe:	
From baseline to Weeks 2, 4, 8, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=45,31,17,51,50)	52.93 (± 18.40)	52.74 (± 20.33)	50.29 (± 21.45)	53.86 (± 23.42)
Week 2: Change from baseline (N=42,31,17,51,48)	-4.00 (± 20.28)	-5.39 (± 21.99)	-11.12 (± 28.14)	-13.75 (± 29.66)
Week 4: Change from baseline (N=43,31,17,50,45)	-9.98 (± 20.84)	-13.00 (± 22.53)	-15.06 (± 24.02)	-23.04 (± 28.32)
Week 8: Change from baseline (N=42,31,16,51,43)	-15.48 (± 21.07)	-16.26 (± 23.71)	-17.88 (± 27.15)	-26.39 (± 24.90)
Week 12: Change from baseline (N=41,30,16,49,41)	-19.37 (± 20.20)	-21.30 (± 22.89)	-15.56 (± 28.70)	-28.33 (± 25.36)
Week 16: Change from baseline (N=41,30,16,50,42)	-15.22 (± 21.72)	-10.73 (± 24.87)	-16.69 (± 24.15)	-19.16 (± 22.43)

End point values	160 mg Elinzanetant (BAY3427080)			
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Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=45,31,17,51,50)	55.36 (\pm 19.71)			
Week 2: Change from baseline (N=42,31,17,51,48)	-10.90 (\pm 21.31)			
Week 4: Change from baseline (N=43,31,17,50,45)	-18.44 (\pm 23.37)			
Week 8: Change from baseline (N=42,31,16,51,43)	-24.09 (\pm 25.51)			
Week 12: Change from baseline (N=41,30,16,49,41)	-27.83 (\pm 24.64)			
Week 16: Change from baseline (N=41,30,16,50,42)	-12.07 (\pm 25.94)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the Menopause-specific Quality-of-Life questionnaire Intervention Version (MenQoL-I) scores at Weeks 4, 8, 12 and 16

End point title	Change from baseline in the Menopause-specific Quality-of-Life questionnaire Intervention Version (MenQoL-I) scores at Weeks 4, 8, 12 and 16
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End point description:

The MenQoL-I is a validated questionnaire used to measure condition-specific quality of life in menopausal women. It is composed of 32 items across four domains (physical, vasomotor, psychosocial and sexual). For each item, subjects recorded whether they had experienced the problem in the past month, and if so, they rated how bothered they were by the problem on a scale of 0 (not at all bothered) to 6 (extremely bothered). The item responses were then converted into analysis scores and an overall questionnaire score. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 4, 8, 12 and 16;

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=46,31,17,51,51)	4.00 (\pm 1.06)	4.38 (\pm 1.16)	4.47 (\pm 1.25)	4.17 (\pm 1.13)
Week 4: Change from baseline (N=42,31,17,50,46)	-0.33 (\pm 0.90)	-0.62 (\pm 1.30)	-0.56 (\pm 0.87)	-1.29 (\pm 1.14)
Week 8: Change from baseline (N=43,31,16,51,43)	-0.62 (\pm 1.10)	-0.87 (\pm 1.25)	-0.91 (\pm 1.06)	-1.45 (\pm 1.18)
Week 12: Change from baseline (N=42,30,16,49,41)	-0.70 (\pm 1.03)	-0.81 (\pm 1.44)	-1.09 (\pm 0.76)	-1.54 (\pm 1.34)

Week 16: Change from baseline (N=42,30,16,50,42)	-0.68 (± 1.01)	-0.76 (± 1.33)	-0.69 (± 0.93)	-1.18 (± 1.13)
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End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=46,31,17,51,51)	4.50 (± 1.23)			
Week 4: Change from baseline (N=42,31,17,50,46)	-1.13 (± 1.09)			
Week 8: Change from baseline (N=43,31,16,51,43)	-1.50 (± 0.99)			
Week 12: Change from baseline (N=42,30,16,49,41)	-1.72 (± 1.32)			
Week 16: Change from baseline (N=42,30,16,50,42)	-1.00 (± 1.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the Beck Depression Inventory II (BDI-II) scores at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in the Beck Depression Inventory II (BDI-II) scores at Weeks 2, 4, 8, 12 and 16
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End point description:

The BDI-II is a 21-item questionnaire assessing the intensity of depressive symptoms over the past 2 weeks. It is composed of items relating to symptoms of depression such as hopelessness and irritability, cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue, weight loss, and lack of interest in sex. Subjects rated each item on a scale of 0 to 3 to give a total score ranging from 0 to 63, with a higher score suggesting more severe depressive symptoms. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=44,31,17,51,50)	11.18 (± 8.74)	14.29 (± 11.36)	10.47 (± 7.01)	9.92 (± 8.62)

Week 2: Change from baseline (N=41,31,17,51,48)	-1.90 (± 5.29)	-2.23 (± 9.27)	-3.06 (± 7.34)	-3.65 (± 6.95)
Week 4: Change from baseline (N=42,31,17,50,45)	-1.55 (± 5.14)	-4.23 (± 9.82)	-2.35 (± 5.16)	-4.08 (± 6.39)
Week 8: Change from baseline (N=41,31,16,51,43)	-2.24 (± 5.26)	-5.32 (± 10.13)	-2.00 (± 8.22)	-4.73 (± 6.34)
Week 12: Change from baseline (N=40,30,16,49,41)	-1.30 (± 7.22)	-5.00 (± 3.80)	-1.69 (± 7.65)	-4.29 (± 6.56)
Week 16: Change from baseline (N=40,30,16,50,42)	-2.43 (± 6.08)	-5.10 (± 11.62)	-0.75 (± 6.71)	-4.04 (± 6.12)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline (N=44,31,17,51,50)	11.48 (± 9.30)			
Week 2: Change from baseline (N=41,31,17,51,48)	-2.71 (± 6.08)			
Week 4: Change from baseline (N=42,31,17,50,45)	-4.13 (± 6.63)			
Week 8: Change from baseline (N=41,31,16,51,43)	-5.51 (± 7.14)			
Week 12: Change from baseline (N=40,30,16,49,41)	-5.73 (± 7.39)			
Week 16: Change from baseline (N=40,30,16,50,42)	-2.36 (± 8.05)			

Statistical analyses

No statistical analyses for this end point

Secondary: Nature and severity of adverse events

End point title	Nature and severity of adverse events
End point description: A Treatment-Emergent Adverse Events (TEAE) is defined as any adverse event (serious and non-serious) with the onset date on or after the date of first dosing with study treatment. Safety Analysis Set.	
End point type	Secondary
End point timeframe: Up to Week 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
Number of TEAEs	28	17	14	34
Number of TEAEs related to IMP	7	7	8	8
Number of Serious TEAEs	2	0	1	1
Number of TEAEs leading to death	0	0	0	0
Number of Severe TEAEs	2	0	1	3

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				
Number of TEAEs	38			
Number of TEAEs related to IMP	12			
Number of Serious TEAEs	1			
Number of TEAEs leading to death	0			
Number of Severe TEAEs	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Elinzanetant Concentrations at Weeks 2, 4, 8 ,12

End point title	Plasma Elinzanetant Concentrations at Weeks 2, 4, 8 ,12 ^[1]
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End point description:

Blood samples for analysis of plasma elinzanetant concentrations were collected at Weeks 2, 4, 8, and 12. A small number of subjects had elinzanetant concentrations below the LOQ for the assay (1.5 ng/mL) at two or more visits (three subjects in each of the 40 mg, 120 mg, and 160 mg groups, four in 80 mg group), indicating that these subjects were non compliant with treatment.

End point type	Secondary
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End point timeframe:

At weeks 2, 4, 8 ,12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint concerns Elinzanetant concentration only, therefore the placebo arm and the baseline is not considered.

End point values	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)	160 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31 ^[2]	17 ^[3]	52 ^[4]	52 ^[5]
Units: ng/ml				
geometric mean (geometric coefficient of variation)				
Week 2	64.254 (± 75.681)	157.207 (± 93.120)	292.929 (± 100.381)	319.552 (± 170.571)
Week 4	78.946 (± 78.892)	118.554 (± 175.865)	253.800 (± 142.944)	398.389 (± 91.644)
Week 8	87.985 (± 68.277)	138.795 (± 72.619)	226.121 (± 79.171)	341.673 (± 145.535)
Week 12	70.138 (± 66.542)	130.729 (± 414.199)	197.041 (± 231.390)	298.896 (± 220.963)

Notes:

[2] - Safety Analysis Set

[3] - Safety Analysis Set

[4] - Safety Analysis Set

[5] - Safety Analysis Set

Statistical analyses

No statistical analyses for this end point

Secondary: Withdrawals due to an adverse event

End point title	Withdrawals due to an adverse event
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End point description:

A Treatment-Emergent Adverse Events (TEAE) is defined as any adverse event (serious and non-serious) with the onset date on or after the date of first dosing with study treatment.

End point type	Secondary
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End point timeframe:

Up to Week 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
TEAEs leading to treatment discontinuation	1	0	2	0
TEAEs leading to study discontinuation	1	0	1	0

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				

TEAEs leading to treatment discontinuation	5			
TEAEs leading to study discontinuation	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects used concomitant medications

End point title	Number of subjects used concomitant medications
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End point description:

A concomitant medication is defined as any medication used on or after date and time of first randomised treatment. All concomitant medications taken during the study were recorded in the eCRF. Any medication that was not specifically prohibited was allowed. (1) Antidiarrheals, intestinal antiinflammatory/antiinfective agents;

End point type	Secondary
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End point timeframe:

Up to week 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
Analgesics	18	8	9	12
Antiinflammatory and antirheumatic products	14	7	5	12
Vitamins	14	6	6	9
Drugs for acid related disorders	13	7	2	10
Psychoanaleptics	6	5	4	10
Psycholeptics	3	7	5	7
Antibacterials for systemic use	9	5	2	5
Drugs for obstructive airway diseases	7	3	3	4
Lipid modifying agents	3	3	4	8
Agents acting on the renin-angiotensin system	7	4	0	11
Thyroid therapy	4	3	3	7
Antihistamines for systemic use	5	4	3	6
Antithrombotic agents	2	4	2	6
Nasal preparations	2	4	1	1
Diuretics	1	2	0	5
Antianemic preparations	5	2	2	5
Mineral supplements	2	2	3	3
Calcium channel blockers	3	0	1	6
Drugs used in diabetes	3	2	0	1
Beta blocking agents	1	2	0	5
Ophthalmologicals	1	1	2	3

Urologicals	1	1	1	3
Antidiarrheals, intestinal agents (1)	2	2	0	0
Antivirals for systemic use	1	3	1	1
Corticosteroids for systemic use	1	1	0	1
Drugs for constipation	2	0	1	3
Anesthetics	0	1	0	3
Antiemetics and antinauseants	2	0	1	1
Drugs for functional gastrointestinal disorders	3	1	0	1
General nutrients	1	1	0	1
Topical products for joint and muscular pain	1	2	0	0
Antifungals for dermatological use	0	1	1	0
Antiobesity preparations, excl. Diet products	0	0	0	2
Corticosteroids, dermatological preparations	1	2	0	1
Cough and cold preparations	3	1	0	2
Other nervous system drugs	1	1	0	1
Unspecified herbal and traditional medicine	1	0	1	1
All other therapeutic products	0	1	0	1
Anti-acne preparations	0	1	0	1
Other alimentary tract and metabolism products	1	1	0	1
Throat preparations	0	1	0	0
Vaccines	0	1	0	1
Antiepileptics	0	0	1	0
Antihemorrhagics	0	0	0	0
Antihypertensives	0	0	1	0
Antiprotozoals	0	0	0	0
Antipruritics, incl. antihistamines, anesthetics	0	0	0	0
Antipsoriatics	0	0	0	0
Bile and liver therapy	0	0	0	1
Drugs for treatment of bone diseases	0	0	1	0
Gynecological antiinfectives and antiseptics	0	0	0	1
Immunosuppressants	0	0	0	1
Other respiratory system products	0	0	0	0
Stomatological preparations	0	0	0	0
Tonics	0	0	0	1
Muscle relaxants	2	0	1	1
Antibiotics,chemotherapeutics (dermatological use)	1	0	0	1
Antimycotics for systemic use	1	0	0	0

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				

Analgesics	16			
Antiinflammatory and antirheumatic products	13			
Vitamins	14			
Drugs for acid related disorders	10			
Psychoanaleptics	9			
Psycholeptics	7			
Antibacterials for systemic use	7			
Drugs for obstructive airway diseases	9			
Lipid modifying agents	4			
Agents acting on the renin-angiotensin system	3			
Thyroid therapy	5			
Antihistamines for systemic use	3			
Antithrombotic agents	4			
Nasal preparations	7			
Diuretics	5			
Antianemic preparations	2			
Mineral supplements	3			
Calcium channel blockers	3			
Drugs used in diabetes	6			
Beta blocking agents	1			
Ophthalmologicals	1			
Urologicals	1			
Antidiarrheals, intestinal agents (1)	3			
Antivirals for systemic use	0			
Corticosteroids for systemic use	3			
Drugs for constipation	1			
Anesthetics	0			
Antiemetics and antinauseants	2			
Drugs for functional gastrointestinal disorders	2			
General nutrients	2			
Topical products for joint and muscular pain	2			
Antifungals for dermatological use	1			
Antiobesity preparations, excl. Diet products	1			
Corticosteroids, dermatological preparations	0			
Cough and cold preparations	0			
Other nervous system drugs	1			
Unspecified herbal and traditional medicine	1			
All other therapeutic products	0			
Anti-acne preparations	0			
Other alimentary tract and metabolism products	0			
Throat preparations	1			
Vaccines	0			
Antiepileptics	0			
Antihemorrhagics	1			
Antihypertensives	0			
Antiprotozoals	1			

Antipruritics, incl. antihistamines, anesthetics	1			
Antipsoriatics	1			
Bile and liver therapy	0			
Drugs for treatment of bone diseases	0			
Gynecological antiinfectives and antiseptics	0			
Immunosuppressants	0			
Other respiratory system products	1			
Stomatological preparations	1			
Tonics	0			
Muscle relaxants	2			
Antibiotics,chemotherapeutics (dermatological use)	0			
Antimycotics for systemic use	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in vital signs (systolic blood pressure) at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in vital signs (systolic blood pressure) at Weeks 2, 4, 8, 12 and 16
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End point description:

Vital signs, including systolic and diastolic blood pressure, pulse rate, temperature, weight, waist circumference, and height, were measured at the time points and recorded in the eCRF. All vital signs were reviewed by the Investigator or delegated physician. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mmHg				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	123.2 (± 10.4)	124.2 (± 10.1)	128.9 (± 9.8)	124.6 (± 10.9)
Week 2: Change from baseline (N=44,31,17,52,51)	0.3 (± 12.5)	-0.2 (± 9.0)	-1.5 (± 12.5)	-2.9 (± 9.3)
Week 4: Change from baseline (N=45,31,17,51,48)	1.7 (± 12.4)	0.1 (± 11.9)	-3.1 (± 9.4)	-4.7 (± 10.7)
Week 8: Change from baseline (N=44,31,16,52,46)	0.5 (± 10.8)	0.5 (± 12.5)	-2.1 (± 10.1)	-1.3 (± 10.0)
Week 12: Change from baseline (N=44,30,16,50,45)	-0.6 (± 12.2)	-2.1 (± 10.9)	-5.9 (± 11.3)	-1.1 (± 10.2)
Week 16: Change from baseline (N=43,30,16,51,45)	3.8 (± 13.3)	-0.9 (± 11.7)	-6.4 (± 11.1)	-1.4 (± 10.8)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mmHg				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	124.0 (± 12.9)			
Week 2: Change from baseline (N=44,31,17,52,51)	-0.8 (± 9.2)			
Week 4: Change from baseline (N=45,31,17,51,48)	-1.3 (± 10.8)			
Week 8: Change from baseline (N=44,31,16,52,46)	-3.8 (± 10.5)			
Week 12: Change from baseline (N=44,30,16,50,45)	-1.3 (± 12.8)			
Week 16: Change from baseline (N=43,30,16,51,45)	2.1 (± 9.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in vital signs (pulse rate) at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in vital signs (pulse rate) at Weeks 2, 4, 8, 12 and 16
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End point description:

Vital signs, including systolic and diastolic blood pressure, pulse rate, temperature, weight, waist circumference, and height, were measured at the time points and recorded in the eCRF. All vital signs were reviewed by the Investigator or delegated physician. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: beats/min				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	69.7 (± 7.8)	71.4 (± 10.3)	70.6 (± 8.7)	70.1 (± 10.2)
Week 2: Change from baseline (N=44,31,17,52,51)	-0.1 (± 8.1)	-0.3 (± 7.3)	-0.7 (± 9.9)	-3.1 (± 9.7)
Week 4: Change from baseline (N=45,31,17,51,48)	-0.6 (± 6.9)	0.5 (± 7.6)	-2.8 (± 8.9)	-1.8 (± 6.4)

Week 8: Change from baseline (N=44,31,16,52,46)	0.4 (± 7.7)	-0.5 (± 8.1)	-3.1 (± 9.8)	-2.8 (± 7.9)
Week 12: Change from baseline (N=44,30,16,50,45)	0.1 (± 9.2)	0.3 (± 8.4)	0.9 (± 8.8)	-1.4 (± 8.8)
Week 16: Change from baseline (N=43,30,16,51,45)	3.2 (± 10.6)	3.3 (± 10.5)	0.0 (± 11.3)	-0.7 (± 8.5)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: beats/min				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	69.7 (± 10.2)			
Week 2: Change from baseline (N=44,31,17,52,51)	2.1 (± 9.4)			
Week 4: Change from baseline (N=45,31,17,51,48)	0.9 (± 7.7)			
Week 8: Change from baseline (N=44,31,16,52,46)	0.3 (± 8.1)			
Week 12: Change from baseline (N=44,30,16,50,45)	0.9 (± 7.4)			
Week 16: Change from baseline (N=43,30,16,51,45)	0.3 (± 8.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in vital signs (temperature) at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in vital signs (temperature) at Weeks 2, 4, 8, 12 and 16
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End point description:

Vital signs, including systolic and diastolic blood pressure, pulse rate, temperature, weight, waist circumference, and height, were measured at the time points and recorded in the eCRF. All vital signs were reviewed by the Investigator or delegated physician. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Celsius (C)				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	36.69 (± 0.43)	36.62 (± 0.32)	36.73 (± 0.30)	36.52 (± 0.46)
Week 2: Change from baseline (N=44,31,17,52,51)	-0.09 (± 0.40)	-0.04 (± 0.28)	0.04 (± 0.26)	0.12 (± 0.50)
Week 4: Change from baseline (N=45,31,17,50,48)	-0.15 (± 0.47)	-0.06 (± 0.34)	0.01 (± 0.41)	0.12 (± 0.46)
Week 8: Change from baseline (N=44,31,16, 52,46)	-0.09 (± 0.38)	-0.01 (± 0.35)	0.00 (± 0.31)	0.11 (± 0.49)
Week 12: Change from baseline (N=44,30,16,50,45)	-0.12 (± 0.44)	-0.12 (± 0.31)	-0.03 (± 0.38)	0.04 (± 0.46)
Week 16: Change from baseline (N=43,30,16,51,45)	-0.07 (± 0.50)	-0.03 (± 0.30)	-0.04 (± 0.32)	0.08 (± 0.41)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Celsius (C)				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	36.68 (± 0.39)			
Week 2: Change from baseline (N=44,31,17,52,51)	-0.01 (± 0.43)			
Week 4: Change from baseline (N=45,31,17,50,48)	-0.06 (± 0.32)			
Week 8: Change from baseline (N=44,31,16, 52,46)	-0.01 (± 0.42)			
Week 12: Change from baseline (N=44,30,16,50,45)	-0.08 (± 0.36)			
Week 16: Change from baseline (N=43,30,16,51,45)	-0.09 (± 0.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in vital signs (weight) at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in vital signs (weight) at Weeks 2, 4, 8, 12 and 16
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End point description:

Vital signs, including systolic and diastolic blood pressure, pulse rate, temperature, weight, waist circumference, and height, were measured at the time points and recorded in the eCRF. All vital signs were reviewed by the Investigator or delegated physician. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Kilogram (Kg)				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	75.85 (± 13.13)	72.65 (± 14.76)	78.14 (± 15.75)	72.36 (± 15.26)
Week 2: Change from baseline (N=44,31,17,52,51)	0.20 (± 1.07)	0.30 (± 1.03)	0.13 (± 1.32)	-0.13 (± 1.19)
Week 4: Change from baseline (N=45,31,17,51,48)	0.23 (± 1.51)	0.08 (± 1.11)	0.12 (± 1.88)	-0.31 (± 1.26)
Week 8: Change from baseline (N=44,31,16,52,46)	0.16 (± 1.98)	0.26 (± 1.59)	-0.11 (± 1.79)	-0.18 (± 1.78)
Week 12: Change from baseline (N=44,30,16,50,45)	-0.02 (± 2.34)	0.58 (± 2.46)	-0.14 (± 2.03)	-0.08 (± 1.93)
Week 16: Change from baseline (N=43,30,16,51,45)	0.17 (± 2.48)	0.39 (± 2.81)	-0.13 (± 2.59)	-0.20 (± 2.13)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Kilogram (Kg)				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	74.11 (± 15.02)			
Week 2: Change from baseline (N=44,31,17,52,51)	0.04 (± 0.84)			
Week 4: Change from baseline (N=45,31,17,51,48)	0.00 (± 1.35)			
Week 8: Change from baseline (N=44,31,16,52,46)	-0.25 (± 2.32)			
Week 12: Change from baseline (N=44,30,16,50,45)	-0.48 (± 2.62)			
Week 16: Change from baseline (N=43,30,16,51,45)	-0.34 (± 2.82)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in vital signs (Body Mass Index) at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in vital signs (Body Mass Index) at Weeks 2, 4, 8, 12 and 16
End point description:	
Vital signs, including systolic and diastolic blood pressure, pulse rate, temperature, weight, waist circumference, and height, were measured at the time points and recorded in the eCRF. All vital signs were reviewed by the Investigator or delegated physician. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.	
End point type	Secondary
End point timeframe:	
From baseline to Weeks 2, 4, 8, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: kg/m ²				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	28.59 (± 3.81)	27.69 (± 4.97)	29.81 (± 4.93)	27.26 (± 4.85)
Week 2: Change from baseline (N=44,31,17,52,51)	0.07 (± 0.41)	0.11 (± 0.39)	0.06 (± 0.5)	-0.04 (± 0.45)
Week 4: Change from baseline (N=45,31,17,51,48)	0.07 (± 0.58)	0.02 (± 0.42)	0.06 (± 0.75)	-0.11 (± 0.49)
Week 8: Change from baseline (N=44,31,16,52,46)	0.04 (± 0.75)	0.09 (± 0.59)	-0.04 (± 0.69)	-0.06 (± 0.66)
Week 12: Change from baseline (N=44,30,16,50,45)	-0.03 (± 0.87)	0.21 (± 0.87)	-0.05 (± 0.79)	-0.02 (± 0.73)
Week 16: Change from baseline (N=43,30,16,51,45)	0.04 (± 0.96)	0.13 (± 1.01)	-0.04 (± 1.01)	-0.07 (± 0.79)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: kg/m ²				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	27.72 (± 4.74)			
Week 2: Change from baseline (N=44,31,17,52,51)	0.01 (± 0.33)			
Week 4: Change from baseline (N=45,31,17,51,48)	0.00 (± 0.53)			
Week 8: Change from baseline (N=44,31,16,52,46)	-0.09 (± 0.88)			
Week 12: Change from baseline (N=44,30,16,50,45)	-0.18 (± 0.99)			
Week 16: Change from baseline (N=43,30,16,51,45)	-0.13 (± 1.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in vital signs (waist circumference) at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in vital signs (waist circumference) at Weeks 2, 4, 8, 12 and 16
End point description:	
Vital signs, including systolic and diastolic blood pressure, pulse rate, temperature, weight, waist circumference, and height, were measured at the time points and recorded in the eCRF. All vital signs were reviewed by the Investigator or delegated physician. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.	
End point type	Secondary
End point timeframe:	
From baseline to Weeks 2, 4, 8, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: cm				
arithmetic mean (standard deviation)				
Baseline (N=46,31,17,50,52)	95.47 (± 11.69)	93.61 (± 13.10)	97.59 (± 13.15)	91.12 (± 13.03)
Week 2: Change from baseline (N=43,31,17,49,51)	0.26 (± 3.99)	0.79 (± 3.55)	-0.91 (± 2.15)	0.13 (± 3.72)
Week 4: Change from baseline (N=44,31,17,48,48)	0.17 (± 4.99)	-0.07 (± 4.23)	-1.26 (± 3.00)	0.05 (± 3.84)
Week 8: Change from baseline (N=43,31,16,50,45)	-0.14 (± 4.45)	-0.11 (± 4.30)	0.04 (± 2.77)	-0.76 (± 4.10)
Week 12: Change from baseline (N=43,30,16,48,45)	-1.72 (± 5.25)	-1.16 (± 4.87)	0.60 (± 2.81)	-0.25 (± 3.97)
Week 16: Change from baseline (N=42,30,16, 49,44)	-0.80 (± 5.46)	-0.99 (± 5.18)	4.33 (± 12.90)	0.02 (± 4.58)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (N=46,31,17,50,52)	92.42 (± 12.36)			
Week 2: Change from baseline (N=43,31,17,49,51)	-0.18 (± 3.90)			
Week 4: Change from baseline (N=44,31,17,48,48)	-0.09 (± 3.97)			
Week 8: Change from baseline (N=43,31,16,50,45)	-0.08 (± 4.71)			

Week 12: Change from baseline (N=43,30,16,48,45)	-0.39 (± 4.42)			
Week 16: Change from baseline (N=42,30,16, 49,44)	-0.24 (± 4.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with normal electrocardiogram (ECG) findings at each visit

End point title	Number of subjects with normal electrocardiogram (ECG) findings at each visit
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End point description:

All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. The Investigator commented on all abnormal findings and determined whether they were Normal, Abnormal not clinically significant, Abnormal clinically significant. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

At Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
Baseline (N=47,31,17,52,52)	38	24	11	31
Week 2 (N= 44,31,17,52,51)	33	23	12	34
Week 4 (N=45,31,17,51,48)	32	23	10	28
Week 8 (N=44,31,17,52,46)	29	21	12	30
Week 12 (N=44,30,16,50,45)	30	22	11	31
Week 16 (N=43,30,16,51,45)	27	26	14	31

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				
Baseline (N=47,31,17,52,52)	34			
Week 2 (N= 44,31,17,52,51)	27			
Week 4 (N=45,31,17,51,48)	31			
Week 8 (N=44,31,17,52,46)	27			
Week 12 (N=44,30,16,50,45)	31			

Week 16 (N=43,30,16,51,45)	28			
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Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in vital signs (diastolic blood pressure) at Weeks 2, 4, 8, 12 and 16

End point title	Change from baseline in vital signs (diastolic blood pressure) at Weeks 2, 4, 8, 12 and 16
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End point description:

Vital signs, including systolic and diastolic blood pressure were measured at the time points and recorded in the eCRF. All vital signs were reviewed by the Investigator or delegated physician. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mmHg				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	80.1 (± 8.0)	78.7 (± 8.5)	79.9 (± 9.1)	78.1 (± 7.6)
Week 2: Change from baseline (N=44,31,16,52,51)	-0.7 (± 6.6)	-1.1 (± 8.4)	-0.8 (± 8.7)	-3.1 (± 7.6)
Week 4: Change from baseline (N=45,31,17,51,48)	-0.2 (± 7.4)	1.2 (± 7.8)	-2.1 (± 6.5)	-2.8 (± 9.1)
Week 8: Change from baseline (N=44,31,16,52,46)	0.2 (± 6.7)	-0.5 (± 6.8)	-3.6 (± 6.9)	-0.6 (± 8.4)
Week 12: Change from baseline (N=44,30,16,50,45)	-0.5 (± 9.6)	-2.8 (± 9.9)	-2.2 (± 7.1)	-1.8 (± 10.3)
Week 16: Change from baseline (N=43,30,16,51,45)	1.6 (± 7.6)	-1.2 (± 8.3)	-3.8 (± 9.7)	-1.9 (± 9.1)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mmHg				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	78.7 (± 10.1)			

Week 2: Change from baseline (N=44,31,16,52,51)	-0.4 (± 7.6)			
Week 4: Change from baseline (N=45,31,17,51,48)	-2.3 (± 8.0)			
Week 8: Change from baseline (N=44,31,16,52,46)	-1.6 (± 7.5)			
Week 12: Change from baseline (N=44,30,16,50,45)	-1.0 (± 9.3)			
Week 16: Change from baseline (N=43,30,16,51,45)	0.6 (± 7.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with abnormal not clinically significant ECG findings at each visit

End point title	Number of subjects with abnormal not clinically significant ECG findings at each visit
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End point description:

All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. The Investigator commented on all abnormal findings and determined whether they were Normal, Abnormal not clinically significant, Abnormal clinically significant.

End point type	Secondary
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End point timeframe:

At Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
Baseline (N=47,31,17,52,52)	9	7	6	21
Week 2 (N=44,31,17,52,51)	11	8	5	18
Week 4 (N=45,31,17,51,48)	13	8	6	23
Week 8 (N=44,31,17,52,46)	15	10	5	21
Week 12 (N=44,30,16,50,45)	14	8	5	19
Week 16 (N=43,30,16,51,45)	16	4	2	20

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				
Baseline (N=47,31,17,52,52)	18			

Week 2 (N=44,31,17,52,51)	24			
Week 4 (N=45,31,17,51,48)	17			
Week 8 (N=44,31,17,52,46)	19			
Week 12 (N=44,30,16,50,45)	14			
Week 16 (N=43,30,16,51,45)	17			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with abnormal clinically significant ECG findings at each visit

End point title	Number of subjects with abnormal clinically significant ECG findings at each visit
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End point description:

All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. The Investigator commented on all abnormal findings and determined whether they were Normal, Abnormal not clinically significant, Abnormal clinically significant. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

At Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
Baseline (N=47,31,17,52,52)	0	0	0	0
Week 2 (N= 44,31,17,52,51)	0	0	0	0
Week 4 (N=45,31,17,51,48)	0	0	1	0
Week 8 (N=44,31,17,52,46)	0	0	0	1
Week 12 (N=44,30,16,50,45)	0	0	0	0
Week 16 (N=43,30,16,51,45)	0	0	0	0

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				
Baseline (N=47,31,17,52,52)	0			
Week 2 (N= 44,31,17,52,51)	0			
Week 4 (N=45,31,17,51,48)	0			
Week 8 (N=44,31,17,52,46)	0			

Week 12 (N=44,30,16,50,45)	0			
Week 16 (N=43,30,16,51,45)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (RR)

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (RR)
End point description:	
All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. The same model of ECG recorder was used throughout the study for any given subject wherever possible. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. Reports were then filed with the subject's medical record. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.	
End point type	Secondary
End point timeframe:	
At Weeks 2, 4, 8, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	913.5 (± 128.5)	891.4 (± 145.6)	934.3 (± 120.3)	927.8 (± 135.5)
Week 2: Change from baseline (N=44,31,17,52,51)	17.3 (± 84.2)	23.0 (± 101.7)	-12.6 (± 99.7)	27.3 (± 94.7)
Week 4: Change from baseline (N=45,31,17,51,48)	1.6 (± 82.8)	24.8 (± 101.9)	20.5 (± 108.5)	27.3 (± 92.6)
Week 8: Change from baseline (N=44,31,17,52,46)	35.8 (± 108.7)	24.8 (± 104.6)	19.0 (± 128.6)	22.3 (± 109.2)
Week 12: Change from baseline (N=44,30,16,50,45)	25.5 (± 143.4)	18.0 (± 110.9)	-23.3 (± 105.1)	27.2 (± 95.9)
Week 16: Change from baseline (N=43,30,16,51,45)	-22.4 (± 135.5)	2.4 (± 138.5)	-25.4 (± 149.6)	5.9 (± 110.8)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mSec				
arithmetic mean (standard deviation)				

Baseline	935.9 (\pm 151.2)			
Week 2: Change from baseline (N=44,31,17,52,51)	-2.6 (\pm 137.7)			
Week 4: Change from baseline (N=45,31,17,51,48)	4.5 (\pm 108.0)			
Week 8: Change from baseline (N=44,31,17,52,46)	-22.6 (\pm 90.1)			
Week 12: Change from baseline (N=44,30,16,50,45)	-1.4 (\pm 107.9)			
Week 16: Change from baseline (N=43,30,16,51,45)	-8.0 (\pm 110.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (PR)

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (PR)
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End point description:

All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. The same model of ECG recorder was used throughout the study for any given subject wherever possible. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. Reports were then filed with the subject's medical record. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

At Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	162.6 (\pm 21.8)	167.8 (\pm 16.5)	162.9 (\pm 21.7)	157.2 (\pm 21.7)
Week 2: Change from baseline (N=44,31,17,52,51)	1.2 (\pm 9.7)	4.6 (\pm 11.7)	5.2 (\pm 11.8)	3.0 (\pm 10.2)
Week 4: Change from baseline (N=45,31,17,51,48)	0.0 (\pm 11.2)	5.9 (\pm 12.3)	2.9 (\pm 12.1)	3.8 (\pm 17.7)
Week 8: Change from baseline (N=44,31,17,52,46)	1.5 (\pm 15.1)	3.6 (\pm 10.4)	-0.1 (\pm 12.3)	4.3 (\pm 10.3)
Week 12: Change from baseline (N=44,30,16,50,45)	1.6 (\pm 11.5)	3.9 (\pm 11.7)	0.7 (\pm 16.2)	1.9 (\pm 11.4)
Week 16: Change from baseline (N=43,30,16,51,45)	0.4 (\pm 11.3)	2.2 (\pm 13.3)	2.4 (\pm 16.0)	2.8 (\pm 11.1)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	164.2 (± 25.8)			
Week 2: Change from baseline (N=44,31,17,52,51)	-2.2 (± 16.3)			
Week 4: Change from baseline (N=45,31,17,51,48)	1.8 (± 13.8)			
Week 8: Change from baseline (N=44,31,17,52,46)	-1.1 (± 14.5)			
Week 12: Change from baseline (N=44,30,16,50,45)	-1.5 (± 16.9)			
Week 16: Change from baseline (N=43,30,16,51,45)	-0.4 (± 13.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (QT)

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (QT)
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End point description:

All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. The same model of ECG recorder was used throughout the study for any given subject wherever possible. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. Reports were then filed with the subject's medical record. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

At Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	394.5 (± 31.2)	397.2 (± 28.7)	403.5 (± 26.9)	402.3 (± 40.3)
Week 2: Change from baseline (N=44,31,17,52,51)	3.6 (± 18.0)	0.2 (± 17.8)	1.1 (± 21.7)	-0.9 (± 35.6)
Week 4: Change from baseline (N=45,31,17,51,48)	4.7 (± 18.5)	-0.1 (± 18.5)	4.8 (± 35.2)	0.2 (± 28.1)
Week 8: Change from baseline (N=44,31,17,52,46)	2.0 (± 19.0)	1.5 (± 17.2)	6.5 (± 28.4)	0.5 (± 34.6)
Week 12: Change from baseline (N=44,30,16,50,45)	1.4 (± 25.1)	0.8 (± 21.6)	-8.9 (± 20.6)	-1.1 (± 32.9)

Week 16: Change from baseline (N=43,30,16,51,45)	-1.7 (± 23.3)	-4.7 (± 24.4)	-3.2 (± 27.6)	-4.1 (± 38.1)
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End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	401.2 (± 28.0)			
Week 2: Change from baseline (N=44,31,17,52,51)	-3.2 (± 25.2)			
Week 4: Change from baseline (N=45,31,17,51,48)	0.8 (± 21.5)			
Week 8: Change from baseline (N=44,31,17,52,46)	-4.0 (± 20.3)			
Week 12: Change from baseline (N=44,30,16,50,45)	1.0 (± 19.5)			
Week 16: Change from baseline (N=43,30,16,51,45)	-2.4 (± 25.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (QTc)

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (QTc)
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End point description:

All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. The same model of ECG recorder was used throughout the study for any given subject wherever possible. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. Reports were then filed with the subject's medical record. QTc: QT corrected interval. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

At Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	410.6 (± 20.9)	417.9 (± 21.4)	416.4 (± 14.1)	415.9 (± 29.3)
Week 2: Change from baseline (N=44,31,17,52,51)	1.6 (± 14.3)	-2.4 (± 11.2)	2.9 (± 14.7)	-4.9 (± 28.2)

Week 4: Change from baseline (N=45,31,17,51,48)	5.6 (± 16.1)	-5.4 (± 11.8)	1.7 (± 19.9)	-2.9 (± 24.5)
Week 8: Change from baseline (N=44,31,17,52,46)	-3.9 (± 18.5)	-3.8 (± 12.3)	2.3 (± 10.8)	-2.2 (± 27.5)
Week 12: Change from baseline (N=44,30,16,50,45)	-2.4 (± 20.8)	-3.2 (± 14.9)	-3.1 (± 14.4)	-4.7 (± 31.3)
Week 16: Change from baseline (N=43,30,16,51,45)	2.8 (± 14.9)	-4.8 (± 13.6)	4.3 (± 17.5)	-4.5 (± 31.2)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	415.2 (± 22.1)			
Week 2: Change from baseline (N=44,31,17,52,51)	-2.1 (± 15.4)			
Week 4: Change from baseline (N=45,31,17,51,48)	0.2 (± 16.3)			
Week 8: Change from baseline (N=44,31,17,52,46)	1.2 (± 14.7)			
Week 12: Change from baseline (N=44,30,16,50,45)	0.5 (± 14.4)			
Week 16: Change from baseline (N=43,30,16,51,45)	-1.6 (± 13.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (QTcF)

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in ECG intervals (QTcF)
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End point description:

All ECGs were performed after the subject had rested for 5 minutes in a semi-recumbent position. The same model of ECG recorder was used throughout the study for any given subject wherever possible. All ECG reports were reviewed, signed and dated by the Investigator or delegated physician. Reports were then filed with the subject's medical record. QTcF: QT interval with Fridericia's correction. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

At Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	407.2 (± 20.6)	413.8 (± 19.9)	413.2 (± 14.3)	413.1 (± 30.7)
Week 2: Change from baseline (N=44,31,17,52,51)	1.2 (± 13.7)	-3.5 (± 10.2)	3.4 (± 13.4)	-4.8 (± 29.5)
Week 4: Change from baseline (N=45,31,17,51,48)	4.8 (± 16.4)	-4.2 (± 11.5)	2.1 (± 23.4)	-3.5 (± 24.7)
Week 8: Change from baseline (N=44,31,17,52,46)	-2.8 (± 15.9)	-2.7 (± 10.9)	4.0 (± 13.2)	-2.6 (± 28.7)
Week 12: Change from baseline (N=44,30,16,50,45)	-1.7 (± 18.5)	-1.9 (± 13.9)	-5.1 (± 13.2)	-5.1 (± 30.8)
Week 16: Change from baseline (N=43,30,16,51,45)	2.6 (± 15.1)	-5.6 (± 14.2)	1.5 (± 14.5)	-4.8 (± 32.7)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mSec				
arithmetic mean (standard deviation)				
Baseline	411.4 (± 18.6)			
Week 2: Change from baseline (N=44,31,17,52,51)	-2.5 (± 15.7)			
Week 4: Change from baseline (N=45,31,17,51,48)	0.4 (± 15.4)			
Week 8: Change from baseline (N=44,31,17,52,46)	-0.4 (± 16.1)			
Week 12: Change from baseline (N=44,30,16,50,45)	1.1 (± 14.6)			
Week 16: Change from baseline (N=43,30,16,51,45)	-1.3 (± 16.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with absolute QTcF values by category at each visit: ≤450, >450 to ≤480, >480 to ≤500, >500 msec

End point title	Number of subjects with absolute QTcF values by category at each visit: ≤450, >450 to ≤480, >480 to ≤500, >500 msec
End point description:	
Absolute QTcF values reported. Number of subjects analyzed at for each reporting group respectively was as follow: Baseline N=47, 31, 17, 52, 52; Week 2 N=44, 31, 17, 52, 52; Week 4 N=45, 31, 17, 51, 48; Week 8 N=44, 31, 17, 52, 46; Week 12 N=44, 30, 16, 50, 45; Week 16 N=43, 30, 16, 51, 45.	
End point type	Secondary

End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
Baseline: <=450 msec	46	30	16	51
Baseline: >450 to <=480 msec	1	1	1	0
Baseline: >480 to <=500 msec	0	0	0	0
Baseline: >500 msec	0	0	0	1
Week 2: <=450 msec	44	30	16	52
Week 2: >450 to <=480 msec	0	1	1	0
Week 2: >480 to <=500 msec	0	0	0	0
Week 2: >500 msec	0	0	0	0
Week 4: <=450 msec	44	30	16	51
Week 4: >450 to <=480 msec	1	1	0	0
Week 4: >480 to <=500 msec	0	0	0	0
Week 4: >500 msec	0	0	1	0
Week 8: <=450 msec	44	30	17	52
Week 8: >450 to <=480 msec	0	1	0	0
Week 8: >480 to <=500 msec	0	0	0	0
Week 8: >500 msec	0	0	0	0
Week 12: <=450 msec	44	30	16	50
Week 12: >450 to <=480 msec	0	0	0	0
Week 12: >480 to <=500 msec	0	0	0	0
Week 12: >500 msec	0	0	0	0
Week 16: <=450 msec	42	30	15	51
Week 16: >450 to <=480 msec	1	0	1	0
Week 16: >480 to <=500 msec	0	0	0	0
Week 16: >500 msec	0	0	0	0

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				
Baseline: <=450 msec	50			
Baseline: >450 to <=480 msec	2			
Baseline: >480 to <=500 msec	0			
Baseline: >500 msec	0			
Week 2: <=450 msec	50			
Week 2: >450 to <=480 msec	1			
Week 2: >480 to <=500 msec	0			

Week 2: >500 msec	0			
Week 4: ≤450 msec	47			
Week 4: >450 to ≤480 msec	1			
Week 4: >480 to ≤500 msec	0			
Week 4: >500 msec	0			
Week 8: ≤450 msec	46			
Week 8: >450 to ≤480 msec	0			
Week 8: >480 to ≤500 msec	0			
Week 8: >500 msec	0			
Week 12: ≤450 msec	45			
Week 12: >450 to ≤480 msec	0			
Week 12: >480 to ≤500 msec	0			
Week 12: >500 msec	0			
Week 16: ≤450 msec	44			
Week 16: >450 to ≤480 msec	1			
Week 16: >480 to ≤500 msec	0			
Week 16: >500 msec	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with change from baseline in ECG QTcF values by category at Weeks 2, 4, 8, 12 and 16: ≤0, >0 to ≤30, >30 to ≤60, >60 msec

End point title	Number of subjects with change from baseline in ECG QTcF values by category at Weeks 2, 4, 8, 12 and 16: ≤0, >0 to ≤30, >30 to ≤60, >60 msec
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End point description:

Increase from Baseline overtime was reported. Number of subjects analyzed at for each reporting group respectively was as follow: Baseline N=47, 31, 17, 52, 52; Week 1 N=44, 31, 17, 52, 52; Week 4 N=45, 31, 17, 51, 48; Week 8 N=44, 31, 17, 52, 46; Week 12 N=44, 30, 16, 50, 45; Week 16 N=43, 30, 16, 51, 45.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Subjects				
Week 2: ≤0 msec	19	21	8	27
Week 2: >0 to ≤30 msec	25	10	8	24
Week 2: >30 to ≤60 msec	0	0	1	1
Week 2: >60 msec	0	0	0	0
Week 4: ≤0 msec	20	20	8	27
Week 4: >0 to ≤30 msec	23	11	8	24
Week 4: >30 to ≤60 msec	2	0	0	0

Week 4: >60 msec	0	0	1	0
Week 8: ≤0 msec	24	20	8	25
Week 8: >0 to ≤30 msec	20	11	9	26
Week 8: >30 to ≤60 msec	0	0	0	1
Week 8: >60 msec	0	0	0	0
Week 12: ≤0 msec	24	15	10	29
Week 12: >0 to ≤30 msec	19	15	6	21
Week 12: >30 to ≤60 msec	1	0	0	0
Week 12: >60 msec	0	0	0	0
Week 16: ≤0 msec	18	18	7	26
Week 16: >0 to ≤30 msec	23	12	9	24
Week 16: >30 to ≤60 msec	2	0	0	1
Week 16: >60 msec	0	0	0	0

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Subjects				
Week 2: ≤0 msec	29			
Week 2: >0 to ≤30 msec	22			
Week 2: >30 to ≤60 msec	0			
Week 2: >60 msec	0			
Week 4: ≤0 msec	24			
Week 4: >0 to ≤30 msec	22			
Week 4: >30 to ≤60 msec	2			
Week 4: >60 msec	0			
Week 8: ≤0 msec	19			
Week 8: >0 to ≤30 msec	26			
Week 8: >30 to ≤60 msec	1			
Week 8: >60 msec	0			
Week 12: ≤0 msec	22			
Week 12: >0 to ≤30 msec	22			
Week 12: >30 to ≤60 msec	1			
Week 12: >60 msec	0			
Week 16: ≤0 msec	24			
Week 16: >0 to ≤30 msec	20			
Week 16: >30 to ≤60 msec	1			
Week 16: >60 msec	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the electronic Columbia Suicide Severity Rating Scale (eC-SSRS) at Weeks 4, 12 and 16

End point title	Change from baseline in the electronic Columbia Suicide Severity Rating Scale (eC-SSRS) at Weeks 4, 12 and 16
End point description:	
The Columbia Suicide Severity Rating Scale (C-SSRS) is a rating scale created to evaluate suicidality in adults and children over the age of 12. It rates an individual's degree of suicidal ideation on a scale, ranging from "wish to be dead" to "active suicidal ideation with specific plan and intent." The version used was the eC-SSRS, which is a subject-reported version of the scale. Shifts from baseline versus post-baseline to demonstrate changes in categories (cat) were reported using cat 1 (No Suicidal Ideation or Behaviour), cat 2 (Suicidal Ideation) and cat 3 (Suicidal Behaviour).	
End point type	Secondary
End point timeframe:	
Baseline to Weeks 4, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42 ^[6]	26 ^[7]	16 ^[8]	44 ^[9]
Units: Subjects				
Week 4: shift from cat 1 to cat 1	34	14	13	38
Week 4: shift from cat 1 to cat 2	1	0	0	0
Week 4: shift from cat 1 to cat 3	0	0	0	0
Week 4: shift from cat 2 to cat 1	5	7	2	4
Week 4: shift from cat 2 to cat 2	1	0	0	0
Week 4: shift from cat 2 to cat 3	0	0	0	0
Week 4: shift from cat 3 to cat 1	1	5	1	2
Week 4: shift from cat 3 to cat 2	0	0	0	0
Week 4: shift from cat 3 to cat 3	0	0	0	0
Week 12: shift from cat 1 to cat 1	34	14	12	40
Week 12: shift from cat 1 to cat 2	0	0	0	0
Week 12: shift from cat 1 to cat 3	0	0	0	0
Week 12: shift from cat 2 to cat 1	7	5	3	2
Week 12: shift from cat 2 to cat 2	0	2	0	1
Week 12: shift from cat 2 to cat 3	0	0	0	0
Week 12: shift from cat 3 to cat 1	1	5	1	2
Week 12: shift from cat 3 to cat 2	0	0	0	0
Week 12: shift from cat 3 to cat 3	0	0	0	0
Week 16: shift from cat 1 to cat 1	33	15	12	40
Week 16: shift from cat 1 to cat 2	0	0	0	0
Week 16: shift from cat 1 to cat 3	0	0	0	0
Week 16: shift from cat 2 to cat 1	6	6	3	4
Week 16: shift from cat 2 to cat 2	1	1	0	0
Week 16: shift from cat 2 to cat 3	0	0	0	0
Week 16: shift from cat 3 to cat 1	1	5	1	2
Week 16: shift from cat 3 to cat 2	0	0	0	0
Week 16: shift from cat 3 to cat 3	0	0	0	0

Notes:

[6] - Week 16 N=41

[7] - Week 16 N=27

[8] - Week 12 N=45; Week 16 N=46

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	46 ^[10]			
Units: Subjects				
Week 4: shift from cat 1 to cat 1	38			
Week 4: shift from cat 1 to cat 2	0			
Week 4: shift from cat 1 to cat 3	0			
Week 4: shift from cat 2 to cat 1	7			
Week 4: shift from cat 2 to cat 2	0			
Week 4: shift from cat 2 to cat 3	0			
Week 4: shift from cat 3 to cat 1	1			
Week 4: shift from cat 3 to cat 2	0			
Week 4: shift from cat 3 to cat 3	0			
Week 12: shift from cat 1 to cat 1	33			
Week 12: shift from cat 1 to cat 2	0			
Week 12: shift from cat 1 to cat 3	0			
Week 12: shift from cat 2 to cat 1	7			
Week 12: shift from cat 2 to cat 2	0			
Week 12: shift from cat 2 to cat 3	0			
Week 12: shift from cat 3 to cat 1	1			
Week 12: shift from cat 3 to cat 2	0			
Week 12: shift from cat 3 to cat 3	0			
Week 16: shift from cat 1 to cat 1	33			
Week 16: shift from cat 1 to cat 2	0			
Week 16: shift from cat 1 to cat 3	0			
Week 16: shift from cat 2 to cat 1	7			
Week 16: shift from cat 2 to cat 2	0			
Week 16: shift from cat 2 to cat 3	0			
Week 16: shift from cat 3 to cat 1	1			
Week 16: shift from cat 3 to cat 2	0			
Week 16: shift from cat 3 to cat 3	0			

Notes:

[10] - Weeks 12 and 16 N=41

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at weeks 2, 4, 12 and 16 for clinical laboratory parameters Hematology: Erythrocytes

End point title	Change from baseline at weeks 2, 4, 12 and 16 for clinical laboratory parameters Hematology: Erythrocytes
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End point description:

Blood samples for clinical hematology assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: 10 ¹² *cells/L				
arithmetic mean (standard deviation)				
Baseline	4.568 (± 0.392)	4.537 (± 0.375)	4.510 (± 0.365)	4.516 (± 0.429)
Week 2: Change from baseline (N=44,31,17,52,51)	-0.106 (± 0.262)	-0.108 (± 0.218)	0.007 (± 0.254)	-0.095 (± 0.215)
Week 4: Change from baseline (N=45,30,17,51,47)	-0.094 (± 0.278)	-0.083 (± 0.217)	0.072 (± 0.200)	-0.087 (± 0.203)
Week 12: Change from baseline (N=44,30,16,49,44)	-0.057 (± 0.277)	-0.085 (± 0.256)	0.039 (± 0.273)	-0.057 (± 0.265)
Week 16: Change from baseline (N=41,30,16,51,45)	-0.060 (± 0.293)	-0.023 (± 0.250)	-0.033 (± 0.290)	-0.085 (± 0.254)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: 10 ¹² *cells/L				
arithmetic mean (standard deviation)				
Baseline	4.563 (± 0.406)			
Week 2: Change from baseline (N=44,31,17,52,51)	-0.090 (± 0.210)			
Week 4: Change from baseline (N=45,30,17,51,47)	-0.077 (± 0.229)			
Week 12: Change from baseline (N=44,30,16,49,44)	-0.057 (± 0.202)			
Week 16: Change from baseline (N=41,30,16,51,45)	-0.040 (± 0.240)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at weeks 2, 4, 12 and 16 for clinical laboratory parameters Hematology: Hematocrit

End point title	Change from baseline at weeks 2, 4, 12 and 16 for clinical laboratory parameters Hematology: Hematocrit
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End point description:

Blood samples for clinical hematology assessment were collected and sent to the central laboratory for

analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
End point timeframe:	
From baseline to weeks 2, 4, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Volume percentage				
arithmetic mean (standard deviation)				
Baseline	0.4230 (± 0.0347)	0.4184 (± 0.0303)	0.4102 (± 0.0384)	0.4088 (± 0.0312)
Week 2: Change from baseline (44,31,17,52,51)	-0.0121 (± 0.0261)	-0.0079 (± 0.0220)	0.0016 (± 0.0211)	-0.0079 (± 0.0195)
Week 4: Change from baseline (N=45,30,17,51,47)	-0.0097 (± 0.0249)	-0.0060 (± 0.0194)	0.0075 (± 0.0144)	-0.0080 (± 0.0186)
Week 12: Change from baseline (N=44,30,16,49,44)	-0.0106 (± 0.0294)	-0.0036 (± 0.0220)	0.0087 (± 0.0276)	-0.0083 (± 0.0258)
Week 16: Change from baseline (N=41,30,16,51,45)	-0.0140 (± 0.0258)	-0.0006 (± 0.0250)	0.0015 (± 0.0244)	-0.0100 (± 0.0235)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Volume percentage				
arithmetic mean (standard deviation)				
Baseline	0.4182 (± 0.0346)			
Week 2: Change from baseline (44,31,17,52,51)	-0.0138 (± 0.0199)			
Week 4: Change from baseline (N=45,30,17,51,47)	-0.0100 (± 0.0234)			
Week 12: Change from baseline (N=44,30,16,49,44)	-0.0115 (± 0.0231)			
Week 16: Change from baseline (N=41,30,16,51,45)	-0.0099 (± 0.0274)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Hematology: Hemoglobin

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical
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End point description:

Blood samples for clinical hematology assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: g/L				
arithmetic mean (standard deviation)				
Baseline	138.4 (± 10.9)	137.3 (± 10.0)	136.4 (± 11.6)	134.6 (± 9.8)
Week 2:Change from baseline (N=44,31,17, 52,51)	-3.0 (± 7.8)	-3.0 (± 6.6)	-0.2 (± 7.5)	-2.8 (± 6.3)
Week 4:Change from baseline (N= 45,30, 17,51,47)	-2.7 (± 8.1)	-2.6 (± 6.7)	2.6 (± 5.3)	2.8 (± 5.7)
Week 12:Change from baseline (N=44,30,16,49,44)	-2.1 (± 7.7)	-2.5 (± 7.5)	0.8 (± 7.5)	-2.3 (± 7.1)
Week 16:Change from baseline (N=41,30, 16,51,45)	-1.9 (± 8.5)	-0.7 (± 6.9)	-1.7 (± 8.2)	-2.6 (± 6.9)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: g/L				
arithmetic mean (standard deviation)				
Baseline	135.6 (± 11.4)			
Week 2:Change from baseline (N=44,31,17, 52,51)	-2.5 (± 5.4)			
Week 4:Change from baseline (N= 45,30, 17,51,47)	-2.4 (± 6.2)			
Week 12:Change from baseline (N=44,30,16,49,44)	-1.5 (± 5.9)			
Week 16:Change from baseline (N=41,30, 16,51,45)	-1.1 (± 6.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in blinical laboratory

parameters Hematology: Erythrocytes Mean Corpuscular Volume

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in blinical laboratory parameters Hematology: Erythrocytes Mean Corpuscular Volume
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End point description:

Blood samples for clinical hematology assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: fL				
arithmetic mean (standard deviation)				
Baseline	92.74 (± 4.65)	92.39 (± 4.51)	90.92 (± 3.00)	90.82 (± 5.25)
Week 2: Change from baseline (N=44,31,17,52,51)	-0.56 (± 2.35)	0.51 (± 2.58)	0.24 (± 2.02)	0.10 (± 1.72)
Week 4: Change from baseline (N=45,30,17,51,47)	-0.22 (± 2.53)	0.49 (± 2.31)	0.27 (± 2.85)	-0.10 (± 1.92)
Week 12: Change from baseline (N=44,30,16,49,44)	-1.22 (± 3.30)	0.98 (± 3.41)	1.18 (± 2.72)	-0.77 (± 2.66)
Week 16: Change from baseline (N= 41, 30,16,51,45)	-1.91 (± 2.99)	0.36 (± 3.41)	1.05 (± 2.39)	-0.55 (± 4.13)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: fL				
arithmetic mean (standard deviation)				
Baseline	91.88 (± 5.69)			
Week 2: Change from baseline (N=44,31,17,52,51)	-1.29 (± 3.35)			
Week 4: Change from baseline (N=45,30,17,51,47)	-0.73 (± 4.48)			
Week 12: Change from baseline (N=44,30,16,49,44)	-1.47 (± 4.49)			
Week 16: Change from baseline (N= 41, 30,16,51,45)	-1.42 (± 5.06)			

Statistical analyses

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Hematology: Leukocytes, Platelets, Basophils, Eosinophils, Lymphocytes, Monocytes and Neutrophils

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Hematology: Leukocytes, Platelets, Basophils, Eosinophils, Lymphocytes, Monocytes and Neutrophils
End point description:	Blood samples for clinical hematology assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are change from baseline.
End point type	Secondary
End point timeframe:	From baseline to weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: 10 ⁹ *cells/L				
arithmetic mean (standard deviation)				
Baseline (Leukocytes) (N=47,31,17,52,52)	6.09 (± 1.80)	6.17 (± 1.89)	6.32 (± 1.35)	6.31 (± 1.74)
Week 2: Leukocytes (N=44,31,17,51,51)	-0.19 (± 1.02)	-0.24 (± 0.99)	-0.13 (± 0.97)	-0.25 (± 1.33)
Week 4: Leukocytes (N=45,30,17,51,47)	0.41 (± 2.80)	-0.09 (± 0.96)	0.16 (± 1.02)	-0.27 (± 1.44)
Week 12: (Leukocytes) (N=44,30,16,49,44)	-0.12 (± 1.28)	-0.11 (± 1.07)	0.08 (± 1.98)	-0.29 (± 1.55)
Week 16: (Leukocytes) (N=41,30,16,51,45)	-0.20 (± 1.15)	0.19 (± 1.84)	-0.05 (± 1.20)	-0.12 (± 1.88)
Baseline (Platelets) (N=47,31,17,51,52)	273.6 (± 53.7)	270.8 (± 66.2)	254.9 (± 37.2)	280.6 (± 62.8)
Week 2: (Platelets) (N=44,31,17,51,51)	0.6 (± 36.2)	-3.9 (± 31.8)	-6.0 (± 22.4)	-5.5 (± 32.4)
Week 4: (Platelets) (N=45,30,17,50,47)	9.5 (± 43.7)	2.1 (± 27.6)	7.6 (± 35.8)	-5.7 (± 29.9)
Week 12: (Platelets) (N=44,30,16,48,44)	8.2 (± 54.7)	-0.5 (± 33.1)	14.7 (± 23.9)	0.0 (± 30.6)
Week 16: (Platelets) (N=41,30,16,50,45)	12.4 (± 28.6)	5.7 (± 37.3)	3.9 (± 28.7)	1.2 (± 32.9)
Baseline (Basophils) (N= 47, 31, 17, 52, 52)	0.03 (± 0.04)	0.05 (± 0.05)	0.04 (± 0.05)	0.03 (± 0.05)
Week 2: (Basophils) (N=44,31,17,52,51)	0.00 (± 0.04)	0.00 (± 0.02)	-0.02 (± 0.04)	0.00 (± 0.04)
Week 4: (Basophils) (N=45,30,17,51,47)	0.00 (± 0.05)	-0.01 (± 0.03)	-0.02 (± 0.04)	-0.01 (± 0.04)
Week 12: (Basophils) (N=44,30,15,49,44)	0.00 (± 0.04)	-0.01 (± 0.04)	-0.02 (± 0.06)	0.00 (± 0.05)
Week 16: (Basophils) (N=41,30,16,51,45)	0.00 (± 0.04)	0.00 (± 0.00)	0.00 (± 0.05)	-0.01 (± 0.04)
Baseline (Eosinophils) (N=47,31,17,52,52)	0.14 (± 0.09)	0.19 (± 0.12)	0.18 (± 0.15)	0.20 (± 0.24)
Week 2: (Eosinophils) (N=44,31,17,52,51)	0.00 (± 0.06)	0.00 (± 0.09)	-0.01 (± 0.07)	-0.03 (± 0.12)

Week 4: (Eosinophils (N=45,30,17,51,47)	-0.01 (± 0.09)	-0.01 (± 0.08)	-0.01 (± 0.11)	-0.03 (± 0.16)
Week 12: (Eosinophils) (N=44,30,15,49,44)	0.02 (± 0.09)	0.02 (± 0.09)	0.00 (± 0.11)	-0.05 (± 0.19)
Week 16: (Eosinophils) (N=41,30,16,51,45)	0.00 (± 0.10)	-0.02 (± 0.08)	-0.01 (± 0.13)	-0.05 (± 0.17)
Baseline (Lymphocytes) (N=47,31,17,52,52)	1.98 (± 0.67)	1.90 (± 0.63)	1.78 (± 0.50)	2.11 (± 0.66)
Week 2: (Lymphocytes) (N=44,31,17,52,51)	-0.06 (± 0.34)	-0.11 (± 0.33)	-0.10 (± 0.31)	-0.11 (± 0.41)
Week 4: (Lymphocytes) (N=45,30,17,51,47)	-0.08 (± 0.38)	-0.13 (± 0.34)	0.04 (± 0.45)	-0.08 (± 0.50)
Week 12: (Lymphocytes) (N=44,30,15,49,44)	-0.05 (± 0.36)	-0.08 (± 0.34)	-0.07 (± 0.24)	-0.09 (± 0.47)
Week 16: (Lymphocytes) (N=41,30,16,51,45)	-0.14 (± 0.46)	-0.11 (± 0.40)	-0.07 (± 0.32)	-0.13 (± 0.39)
Baseline (Monocytes) (N=47,31,17,52,52)	0.44 (± 0.13)	0.47 (± 0.14)	0.51 (± 0.10)	0.47 (± 0.14)
Week 2: (Monocytes) (N=44,31,17,52,51)	0.00 (± 0.09)	-0.02 (± 0.13)	-0.02 (± 0.13)	-0.05 (± 0.14)
Week 4: (Monocytes) (N=45,30,17,51,47)	0.02 (± 0.09)	-0.03 (± 0.10)	0.01 (± 0.12)	-0.03 (± 0.11)
Week 12: (Monocytes) (N=44,30,15,49,44)	0.01 (± 0.11)	-0.03 (± 0.10)	-0.06 (± 0.11)	-0.03 (± 0.13)
Week 16: (Monocytes) (N=41,30,16,51,45)	0.01 (± 0.11)	-0.02 (± 0.14)	-0.03 (± 0.13)	0.00 (± 0.13)
Baseline (Neutrophils) (N=47,31,17,52,52)	3.50 (± 1.34)	3.59 (± 1.33)	3.81 (± 1.13)	3.51 (± 1.41)
Week 2: (Neutrophils) (N=44,31,17,52,51)	-0.14 (± 0.79)	-0.15 (± 0.84)	0.03 (± 0.80)	-0.08 (± 1.24)
Week 4: (Neutrophils) (N=45,30,17,51,47)	0.11 (± 1.04)	0.09 (± 0.86)	0.14 (± 0.70)	-0.13 (± 1.24)
Week 12: (Neutrophils) (N=44,30,16,49,44)	-0.11 (± 1.16)	-0.02 (± 0.97)	0.22 (± 1.79)	-0.13 (± 1.26)
Week 16: (Neutrophils) (N=41,30,16,51,45)	-0.08 (± 1.19)	0.33 (± 1.70)	0.05 (± 0.96)	0.04 (± 1.73)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: 10 ⁹ *cells/L				
arithmetic mean (standard deviation)				
Baseline (Leukocytes) (N=47,31,17,52,52)	6.40 (± 1.76)			
Week 2:Leukocytes N=44,31,17,51,51	-0.12 (± 1.44)			
Week 4: Leukocytes N=45,30,17,51,47	-0.20 (± 1.04)			
Week 12: (Leukocytes) (N=44,30,16,49,44)	-0.08 (± 1.59)			
Week 16: (Leukocytes) (N=41,30,16,51,45)	0.09 (± 1.18)			
Baseline (Platelets) (N=47,31,17,51,52)	277.0 (± 59.3)			
Week 2: (Platelets) (N=44,31,17,51,51)	-3.0 (± 30.7)			
Week 4: (Platelets) (N=45,30,17,50,47)	-1.4 (± 34.4)			

Week 12: (Platelets) (N=44,30,16,48,44)	1.3 (± 45.7)			
Week16: (Platelets) (N=41,30,16,50,45)	9.5 (± 38.0)			
Baseline (Basophils) (N= 47, 31, 17, 52, 52)	0.03 (± 0.04)			
Week 2: (Basophils) (N= 44,31,17,52,51)	0.01 (± 0.04)			
Week 4: (Basophils) (N=45,30,17,51,47)	0.01 (± 0.05)			
Week 12: (Basophils) (N=44,30,15,49,44)	0.00 (± 0.03)			
Week 16: (Basophils) (N=41,30,16,51,45)	0.01 (± 0.05)			
Baseline (Eosinophils) (N=47,31,17,52,52)	0.18 (± 0.14)			
Week 2: (Eosinophils) (N= 44,31,17,52,51)	-0.02 (± 0.09)			
Week 4: (Eosinophils) (N= 45,30,17,51,47)	-0.02 (± 0.07)			
Week 12: (Eosinophils) (N=44,30,15,49,44)	-0.03 (± 0.09)			
Week 16: (Eosinophils) (N=41,30,16,51,45)	-0.02 (± 0.11)			
Baseline (Lymphocytes) (N=47,31,17,52,52)	2.00 (± 0.62)			
Week 2: (Lymphocytes) (N=44,31,17,52,51)	-0.14 (± 0.39)			
Week 4: (Lymphocytes) (N=45,30,17,51,47)	-0.02 (± 0.38)			
Week 12: (Lymphocytes) (N=44,30,15,49,44)	-0.05 (± 0.29)			
Week 16: (Lymphocytes) (N=41,30,16,51,45)	0.01 (± 0.36)			
Baseline (Monocytes) (N=47,31,17,52, 52)	0.46 (± 0.17)			
Week 2: (Monocytes) (N=44,31,17,52,51)	-0.01 (± 0.11)			
Week 4: (Monocytes) (N=45,30,17,51,47)	-0.02 (± 0.12)			
Week 12: (Monocytes) (N=44,30,15,49,44)	0.00 (± 0.15)			
Week 16: (Monocytes) (N=41,30,16,51,45)	0.00 (± 0.14)			
Baseline (Neutrophils) (N=47,31,17,52, 52)	3.73 (± 1.28)			
Week 2: (Neutrophils) (N=44,31,17,52,51)	0.01 (± 1.32)			
Week 4: (Neutrophils) (N=45,30,17,51,47)	-0.16 (± 0.91)			
Week 12: (Neutrophils) (N= 44,30,16,49,44)	-0.01 (± 1.39)			
Week 16: (Neutrophils) (N=41,30,16,51,45)	0.10 (± 0.95)			

Statistical analyses

Secondary: Change from baseline at weeks 2, 4, 12 and 16 in clinical laboratory parameters Hematology: Leukocytes, Basophils, Eosinophils, Lymphocytes, Monocytes and Neutrophils

End point title	Change from baseline at weeks 2, 4, 12 and 16 in clinical laboratory parameters Hematology: Leukocytes, Basophils, Eosinophils, Lymphocytes, Monocytes and Neutrophils
End point description:	
Blood samples for clinical hematology assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are change from baseline.	
End point type	Secondary
End point timeframe:	
From baseline to weeks 2, 4, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Percentage of total white blood cells				
arithmetic mean (standard deviation)				
Baseline Basophils/ Leukocytes N=47,31,17,52,52	0.61 (± 0.36)	0.72 (± 0.34)	0.59 (± 0.26)	0.69 (± 0.47)
Week 2: Basophils/ Leukocytes N=44,31,17,52,51	0.02 (± 0.22)	-0.01 (± 0.19)	-0.01 (± 0.18)	-0.04 (± 0.30)
Week 4: Basophils/ Leukocytes N=45,30,17,51,47	0.03 (± 0.28)	-0.04 (± 0.21)	-0.02 (± 0.02)	-0.06 (± 0.31)
Week 12: Basophils/ Leukocytes) N=44,30,15,49,44	0.02 (± 0.35)	0.01 (± 0.26)	0.03 (± 0.15)	-0.07 (± 0.31)
Week 16: Basophils/ Leukocytes)N=41,30,16,51,45	0.00 (± 0.27)	0.05 (± 0.20)	0.06 (± 0.22)	-0.05 (± 0.32)
Baseline Eosinophils/ Leukocytes N=47,31,17,52,52	2.17 (± 1.22)	2.89 (± 1.67)	2.66 (± 1.80)	2.97 (± 3.43)
Week 2: Eosinophils/ Leukocytes N=44,31,17,52,51	0.16 (± 0.87)	0.20 (± 1.01)	-0.12 (± 0.75)	-0.24 (± 1.78)
Week 4: Eosinophils/ Leukocytes N=45,30,17,51,47	-0.13 (± 0.84)	-0.06 (± 0.99)	-0.15 (± 1.14)	-0.43 (± 2.43)
Week 12: Eosinophils/ Leukocytes N=44,30,15,49,44	0.33 (± 1.22)	0.41 (± 1.49)	0.11 (± 1.16)	-0.53 (± 2.58)
Week16: Eosinophils/ Leukocytes N=41,30,16,51,45	0.10 (± 1.59)	-0.15 (± 1.18)	0.00 (± 1.53)	-0.42 (± 2.33)
Baseline Lymphocytes/ Leukocytes N=47,31,17,52,52	32.87 (± 7.02)	31.31 (± 6.31)	28.71 (± 7.07)	34.20 (± 9.42)
Week 2: Lymphocytes/ Leukocytes N=44,31,17,52,51	0.27 (± 5.12)	-0.54 (± 5.60)	-1.32 (± 4.45)	-0.83 (± 7.48)
Week 4: Lymphocytes/ Leukocytes N=45,30,17,51,47	-1.24 (± 5.98)	-1.25 (± 5.12)	-0.89 (± 3.68)	-0.43 (± 7.03)
Week 12: Lymphocytes/ Leukocytes N=44,30,15,49,44	-0.32 (± 6.82)	-0.51 (± 6.59)	0.13 (± 4.78)	-0.41 (± 6.56)
Week 16: Lymphocytes/ Leukocytes N=41,30,16,51,45	-0.89 (± 7.90)	-1.40 (± 8.07)	-0.75 (± 4.70)	-0.95 (± 7.10)
Baseline Monocytes/Leukocytes N=47,31,17,52,52	7.41 (± 1.76)	7.71 (± 2.07)	8.18 (± 1.62)	7.55 (± 1.67)

Week 2: Monocytes/Leukocytes N=44,31,17,52,51	0.19 (± 1.11)	0.05 (± 1.83)	-0.24 (± 2.01)	-0.36 (± 1.59)
Week 4: Monocytes/Leukocytes N=45,30,17,51,47	0.24 (± 1.31)	-0.19 (± 1.24)	-0.29 (± 1.71)	-0.13 (± 1.25)
Week 12: Monocytes/Leukocytes N=44,30,15,49,44	0.45 (± 1.34)	-0.19 (± 1.64)	-0.67 (± 1.27)	-0.01 (± 1.57)
Week 16: Monocytes/Leukocytes N=41,30,16,51,45	0.48 (± 1.67)	-0.50 (± 1.75)	-0.48 (± 1.45)	0.27 (± 1.67)
Baseline Neutrophils/Leukocytes N=47,31,17,52,52	56.93 (± 8.12)	57.37 (± 7.13)	59.85 (± 8.07)	54.59 (± 0.43)
Week 2: Neutrophils/Leukocytes N=44,31,17,52,51	-0.64 (± 6.11)	0.29 (± 6.64)	1.70 (± 5.11)	1.47 (± 8.32)
Week 4: Neutrophils/Leukocytes N=45,30,17,51,47	1.10 (± 6.92)	1.54 (± 5.78)	1.35 (± 4.76)	1.05 (± 8.38)
Week 12: Neutrophils/Leukocytes N=44,30,15,49,44	-0.48 (± 7.92)	0.27 (± 7.61)	0.40 (± 5.40)	1.01 (± 7.54)
Week 16: Neutrophils/Leukocytes N=41,30,16,51,45	0.30 (± 9.57)	2.00 (± 9.27)	1.17 (± 5.31)	1.14 (± 8.14)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Percentage of total white blood cells				
arithmetic mean (standard deviation)				
Baseline Basophils/ Leukocytes N=47,31,17,52,52	0.59 (± 0.31)			
Week 2: Basophils/ Leukocytes N=44,31,17,52,51	0.07 (± 0.20)			
Week 4: Basophils/ Leukocytes N=45,30,17,51,47	0.08 (± 0.30)			
Week 12: Basophils/ Leukocytes) N=44,30,15,49,44	0.05 (± 0.21)			
Week 16: Basophils/ Leukocytes)N=41,30,16,51,45	0.01 (± 0.19)			
Baseline Eosinophils/ Leukocytes N=47,31,17,52,52	2.76 (± 1.78)			
Week 2: Eosinophils/ Leukocytes N=44,31,17,52,51	-0.13 (± 1.17)			
Week 4: Eosinophils/ Leukocytes N=45,30,17,51,47	-0.17 (± 0.99)			
Week 12: Eosinophils/ Leukocytes N=44,30,15,49,44	-0.27 (± 1.43)			
Week16: Eosinophils/ Leukocytes N=41,30,16,51,45	-0.32 (± 1.57)			
Baseline Lymphocytes/ Leukocytes N=47,31,17,52,52	31.95 (± 7.49)			
Week 2: Lymphocytes/ Leukocytes N=44,31,17,52,51	-1.37 (± 6.02)			
Week 4: Lymphocytes/ Leukocytes N=45,30,17,51,47	0.68 (± 4.85)			
Week 12: Lymphocytes/ Leukocytes N=44,30,15,49,44	-0.07 (± 4.94)			
Week 16: Lymphocytes/ Leukocytes N=41,30,16,51,45	-0.70 (± 4.39)			

Baseline Monocytes/Leukocytes N=47,31,17,52,52	7.15 (± 1.67)			
Week 2: Monocytes/Leukocytes N=44,31,17,52,51	0.08 (± 1.20)			
Week 4: Monocytes/Leukocytes N=45,30,17,51,47	0.21 (± 1.81)			
Week 12: Monocytes/Leukocytes N=44,30,15,49,44	0.24 (± 1.52)			
Week 16: Monocytes/Leukocytes N=41,30,16,51,45	0.08 (± 1.68)			
Baseline Neutrophils/Leukocytes N=47,31,17,52,52	57.56 (± 8.01)			
Week 2: Neutrophils/Leukocytes N=44,31,17,52,51	1.36 (± 6.75)			
Week 4: Neutrophils/Leukocytes N=45,30,17,51,47	-0.80 (± 6.01)			
Week 12: Neutrophils/Leukocytes N=44,30,15,49,44	0.05 (± 5.60)			
Week 16: Neutrophils/Leukocytes N=41,30,16,51,45	0.94 (± 5.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary: Change from baseline at weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Sodium, Potassium, Glucose, Urea Nitrogen, Calcium, Phosphate, Bicarbonate, Magnesium and Chloride

End point title	Secondary: Change from baseline at weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Sodium, Potassium, Glucose, Urea Nitrogen, Calcium, Phosphate, Bicarbonate, Magnesium and Chloride
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End point description:

Blood samples for clinical chemistry assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mmol/L				
arithmetic mean (standard deviation)				
Baseline (Sodium) (N=47, 31, 17,52, 52)	141.3 (± 2.0)	141.6 (± 2.4)	141.6 (± 2.9)	141.2 (± 1.8)
Week 2: (Sodium) (N=43,31,17,51,51)	-0.1 (± 1.9)	0.1 (± 2.1)	-0.6 (± 2.0)	-0.5 (± 1.8)
Week 4: (Sodium) (N=45,31,17,51,48)	-0.5 (± 1.7)	-0.2 (± 2.1)	-0.9 (± 2.4)	-0.3 (± 1.8)
Week 8: (Sodium) (N=41,30,14,50,43)	0.0 (± 1.8)	-0.8 (± 2.5)	-0.6 (± 1.6)	0.1 (± 2.0)

Week 12: (Sodium) (N=44,30,16,49,44)	-0.5 (± 1.9)	-0.6 (± 2.5)	-0.9 (± 1.7)	0.0 (± 2.2)
Week 16: (Sodium) (N=43,30,16,51,45)	-0.2 (± 1.7)	-0.1 (± 2.1)	-0.1 (± 2.0)	-0.2 (± 2.0)
Baseline (Potassium) (N=47, 31, 17,52, 52)	4.51 (± 0.38)	4.43 (± 0.3)	4.23 (± 0.33)	4.37 (± 0.44)
Week 2: (Potassium) (N=43,31,17,51,51)	-0.02 (± 0.35)	-0.08 (± 0.36)	0.06 (± 0.35)	0.01 (± 0.44)
Week 4: (Potassium) (N=45,31,17,50,47)	-0.04 (± 0.39)	-0.09 (± 0.4)	0.06 (± 0.27)	-0.02 (± 0.45)
Week 8: (Potassium) (N=41,30,13,50,43)	0.06 (± 0.39)	-0.1 (± 0.34)	-0.05 (± 0.3)	0.02 (± 0.51)
Week 12: (Potassium) (N=44,30,16,49, 44)	-0.1 (± 0.4)	-0.07 (± 0.34)	0.1 (± 0.41)	0.03 (± 0.51)
Week 16: (Potassium) (N=43,30,16,51,44)	-0.13 (± 0.39)	-0.1 (± 0.33)	-0.04 (± 0.33)	0.04 (± 0.45)
Baseline (Glucose) (N=47, 31, 17,52, 52)	5.06 (± 0.83)	5.32 (± 1.11)	5.16 (± 0.71)	5.04 (± 0.74)
Week 2: (Glucose) (N=43,31,17,51,51)	0.22 (± 1.12)	-0.07 (± 0.92)	0.04 (± 1.01)	0.28 (± 0.97)
Week 4: (Glucose) (N=45,31,17,51,47)	0.24 (± 0.73)	0.02 (± 0.87)	-0.24 (± 1.08)	0.02 (± 0.87)
Week 8: (Glucose) (N=41,30,13,50,43)	0.12 (± 0.54)	-0.15 (± 1.15)	-0.13 (± 1.17)	0.01 (± 1.09)
Week 12: (Glucose) (N=44,30 16,49,44)	-0.06 (± 0.94)	-0.09 (± 1.06)	0.13 (± 0.55)	0.21 (± 1.48)
Week 16: (Glucose) (N=43,30,16,51,44)	0.14 (± 0.81)	0.06 (± 1.03)	0.10 (± 0.94)	0.09 (± 1.02)
Baseline (Urea Nitrogen) (N=47, 31, 17,52, 52)	5.74 (± 1.49)	5.64 (± 1.54)	5.70 (± 1.45)	5.34 (± 1.51)
Week 2: (Urea Nitrogen) (N=43,31,17,51,51)	-0.43 (± 1.05)	0.04 (± 1.21)	0.50 (± 1.35)	0.50 (± 1.25)
Week 4: (Urea Nitrogen) (N=45,31,17,51,47)	-0.30 (± 1.58)	0.12 (± 0.95)	0.17 (± 1.25)	0.36 (± 1.42)
Week 8: (Urea Nitrogen) (N=41,30,14,50,43)	-0.23 (± 1.10)	-0.34 (± 1.18)	0.13 (± 1.71)	0.53 (± 1.58)
Week 12: (Urea Nitrogen) (N=44,30,16,49,44)	-0.21 (± 1.20)	-0.17 (± 1.13)	0.45 (± 2.11)	0.31 (± 1.09)
Week 16: (Urea Nitrogen) (N=43,30,16,51,45)	-0.24 (± 1.41)	-0.19 (± 1.32)	-0.03 (± 1.57)	0.24 (± 1.11)
Baseline (Calcium) (N=47,31,17,52,52)	2.348 (± 0.082)	2.354 (± 0.093)	2.325 (± 0.091)	2.347 (± 0.117)
Week 2: (Calcium) (N=43,31,17,51,51)	-0.046 (± 0.081)	-0.052 (± 0.082)	0.011 (± 0.102)	-0.019 (± 0.079)
Week 4: (Calcium) (N=45,31,17,51,48)	-0.035 (± 0.094)	-0.035 (± 0.077)	0.028 (± 0.068)	-0.018 (± 0.099)
Week 8: (Calcium) (N=41,30,14,50,43)	-0.008 (± 0.109)	-0.034 (± 0.085)	0.002 (± 0.091)	-0.021 (± 0.108)
Week 12: (Calcium) (N=44,30,16,49,44)	-0.006 (± 0.088)	-0.018 (± 0.091)	0.014 (± 0.108)	-0.014 (± 0.097)
Week 16 (Calcium) (N=43,30,16,51,45)	-0.005 (± 0.090)	-0.033 (± 0.093)	0.003 (± 0.097)	-0.009 (± 0.100)
Baseline (Phosphate) (N=47, 31, 17,52, 52)	1.28 (± 0.15)	1.28 (± 0.15)	1.17 (± 0.15)	1.26 (± 0.16)
Week 2: (Phosphate) (N=43,31,17,51,51)	-0.02 (± 0.13)	0.00 (± 0.13)	0.03 (± 0.15)	0.00 (± 0.15)
Week 4: (Phosphate) (N=45,31,17,5,47)	0.00 (± 0.14)	0.00 (± 0.16)	0.05 (± 0.09)	-0.011 (± 0.15)
Week 8: (Phosphate) (N=41,30,13,50,43)	-0.01 (± 0.13)	-0.02 (± 0.15)	0.07 (± 0.11)	0.02 (± 0.18)
Week 12: (Phosphate) (N=44,30,16,49,44)	-0.02 (± 0.16)	-0.02 (± 0.17)	0.06 (± 0.15)	0.02 (± 0.19)
Week 16: (Phosphate) (N=43,30,16,51,44)	-0.02 (± 0.17)	-0.01 (± 0.16)	0.00 (± 0.14)	-0.01 (± 0.17)
Baseline (Bicarbonate) (N=47, 31, 17,52, 52)	25.5 (± 2.4)	26.6 (± 3.4)	26.2 (± 3.7)	26.7 (± 2.7)

Week 2: (Bicarbonate) (N=43,31,17,51,51)	0.3 (± 1.7)	0.0 (± 2.0)	-0.6 (± 2.3)	-0.5 (± 2.1)
Week 4: (Bicarbonate) (N=45,31,17,51,48)	0.2 (± 2.0)	-0.1 (± 2.0)	-0.1 (± 2.3)	-0.4 (± 2.1)
Week 8: (Bicarbonate) (N=41,30,14,50,43)	0.3 (± 1.8)	0.0 (± 2.3)	-0.2 (± 2.1)	-0.6 (± 1.9)
Week 12: (Bicarbonate) (N=44,30,16,49,44)	0.6 (± 2.1)	-0.4 (± 2.1)	-0.5 (± 2.4)	-0.6 (± 1.9)
Week 16: (Bicarbonate) (N=43,30,16,51,45)	0.4 (± 1.5)	-0.1 (± 2.3)	-0.5 (± 2.7)	-0.3 (± 2.3)
Baseline (Magnesium) (N=47, 31, 17,52, 52)	0.809 (± 0.075)	0.833 (± 0.084)	0.827 (± 0.075)	0.821 (± 0.067)
Week 2: (Magnesium) (N=44,31,17,51,51)	-0.011 (± 0.066)	-0.027 (± 0.070)	-0.009 (± 0.065)	-0.013 (± 0.066)
Week 4: (Magnesium) (N=45,31,17,51,48)	-0.008 (± 0.054)	-0.035 (± 0.057)	0.002 (± 0.052)	-0.017 (± 0.061)
Week 8: (Magnesium) (N=41,30,14,50,43)	0.005 (± 0.056)	-0.017 (± 0.065)	0.010 (± 0.048)	0.005 (± 0.077)
Week 12: (Magnesium) (N=44,30,16, 49,44)	-0.033 (± 0.059)	-0.025 (± 0.060)	-0.035 (± 0.058)	-0.012 (± 0.070)
Week 16: (Magnesium) (N=43,30,16,51,45)	-0.024 (± 0.052)	-0.043 (± 0.069)	-0.022 (± 0.063)	-0.025 (± 0.057)
Baseline (Chloride) (N=47, 31, 17,52, 52)	105.6 (± 2.2)	105.4 (± 2.1)	105.5 (± 2.4)	104.8 (± 2.4)
Week 2: (Chloride) (N=44,31,17,51,51)	0.2 (± 2.0)	0.3 (± 2.2)	0.3 (± 2.2)	0.5 (± 2.2)
Week 4: (Chloride) (N=45,31,17,51,48)	-0.3 (± 1.7)	-0.2 (± 1.8)	-0.7 (± 2.5)	0.3 (± 2.2)
Week 8: (Chloride) (N=41,30,14,50,43)	0.2 (± 1.9)	-0.3 (± 2.0)	-0.4 (± 1.8)	0.5 (± 2.3)
Week 12: (Chloride) (N=44,30,16,49,44)	-0.5 (± 2.2)	-0.1 (± 2.2)	-0.3 (± 1.9)	0.5 (± 2.3)
Week 16: (Chloride) (N=43,30,16,51,44)	-0.5 (± 1.8)	0.2 (± 2.2)	0.6 (± 2.6)	0.1 (± 1.9)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mmol/L				
arithmetic mean (standard deviation)				
Baseline (Sodium) (N=47, 31, 17,52, 52)	141.3 (± 2.0)			
Week 2: (Sodium) (N=43,31,17,51,51)	-0.5 (± 1.7)			
Week 4: (Sodium) (N=45,31,17,51,48)	0.0 (± 1.6)			
Week 8: (Sodium) (N=41,30,14,50,43)	0.1 (± 1.7)			
Week 12: (Sodium) (N=44,30,16,49,44)	-0.1 (± 1.8)			
Week 16: (Sodium) (N=43,30,16,51,45)	-0.3 (± 1.8)			
Baseline (Potassium) (N=47, 31, 17,52, 52)	4.36 (± 0.45)			
Week 2: (Potassium) (N=43,31,17,51,51)	-0.07 (± 0.4)			
Week 4: (Potassium) (N=45,31,17,50,47)	-0.13 (± 0.31)			
Week 8: (Potassium) (N=41,30,13,50,43)	-0.11 (± 0.42)			
Week 12: (Potassium) (N=44,30,16,49, 44)	-0.16 (± 0.4)			

Week 16: (Potassium) (N=43,30,16,51,44)	-0.16 (± 0.4)			
Baseline (Glucose) (N=47, 31, 17,52, 52)	5.81 (± 2.7)			
Week 2: (Glucose) (N=43,31,17,51,51)	0.21 (± 1.89)			
Week 4: (Glucose) (N=45,31,17,51,47)	-0.29 (± 2.39)			
Week 8: (Glucose) (N=41,30,13,50,43)	-0.12 (± 1.35)			
Week 12: (Glucose) (N=44,30 16,49,44)	-0.34 (± 1.82)			
Week 16: (Glucose) (N=43,30,16,51,44)	-0.43 (± 1.58)			
Baseline (Urea Nitrogen) (N=47, 31, 17,52, 52)	5.31 (± 1.26)			
Week 2: (Urea Nitrogen) (N=43,31,17,51,51)	0.24 (± 1.15)			
Week 4: (Urea Nitrogen) N=45,31,17,51,47)	0.12 (± 1.22)			
Week 8: (Urea Nitrogen) (N=41,30,14,50,43)	-0.03 (± 1.34)			
Week 12: (Urea Nitrogen) N=44,30,16,49,44)	-0.10 (± 1.31)			
Week 16: (Urea Nitrogen) (N=43,30,16,51,45)	-0.01 (± 1.25)			
Baseline (Calcium) (N=47,31,17,52,52)	2.342 (± 0.091)			
Week 2: (Calcium) (N=43,31,17,51,51)	-0.050 (± 0.101)			
Week 4: (Calcium) N=45,31,17,51,48)	-0.036 (± 0.094)			
Week 8: (Calcium) (N=41,30,14,50,43)	-0.042 (± 0.077)			
Week 12: (Calcium) N=44,30,16,49,44)	-0.042 (± 0.084)			
Week 16 (Calcium) (N=43,30,16,51,45)	-0.027 (± 0.104)			
Baseline (Phosphate) (N=47, 31, 17,52, 52)	1.22 (± 0.15)			
Week 2: (Phosphate) (N=43,31,17,51,51)	-0.02 (± 0.17)			
Week 4: (Phosphate) (N=45,31,17,5,47)	-0.03 (± 0.15)			
Week 8: (Phosphate) (N=41,30,13,50,43)	-0.02 (± 0.14)			
Week 12: (Phosphate) (N=44,30,16,49,44)	-0.06 (± 0.14)			
Week 16: (Phosphate) (N=43,30,16,51,44)	-0.01 (± 0.13)			
Baseline (Bicarbonate) (N=47, 31, 17,52, 52)	26.0 (± 2.9)			
Week 2: (Bicarbonate) (N=43,31,17,51,51)	-0.2 (± 2.0)			
Week 4: (Bicarbonate) (N=45,31,17,51,48)	0.0 (± 1.7)			
Week 8: (Bicarbonate) (N=41,30,14,50,43)	0.3 (± 1.9)			
Week 12: (Bicarbonate) (N=44,30,16,49,44)	-0.2 (± 1.9)			
Week 16: (Bicarbonate) (N=43,30,16,51,45)	-0.1 (± 2.1)			
Baseline (Magnesium) (N=47, 31, 17,52, 52)	0.817 (± 0.076)			

Week 2: (Magnesium) (N=44,31,17,51,51)	-0.037 (± 0.057)			
Week 4: (Magnesium) (N=45,31,17,51,48)	-0.017 (± 0.060)			
Week 8: (Magnesium) (N=41,30,14,50,43)	-0.008 (± 0.063)			
Week 12: (Magnesium) (N=44,30,16,49,44)	-0.016 (± 0.059)			
Week 16: (Magnesium) (N=43,30,16,51,45)	-0.02 (± 0.052)			
Baseline (Chloride) (N=47, 31, 17,52, 52)	105.3 (± 2.6)			
Week 2: (Chloride) (N=44,31,17,51,51)	-0.1 (± 1.9)			
Week 4: (Chloride) (N=45,31,17,51,48)	0.2 (± 2.1)			
Week 8: (Chloride) (N=41,30,14,50,43)	0.3 (± 1.6)			
Week 12: (Chloride) (N=44,30,16,49,44)	0.8 (± 2.0)			
Week 16: (Chloride) (N=43,30,16,51,44)	0.1 (± 2.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Creatinine and Bilirubin

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Creatinine and Bilirubin
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End point description:

Blood samples for clinical chemistry assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: umol/L				
arithmetic mean (standard deviation)				
Baseline (Creatinine) (N=47,31,17,52,52)	68.8 (± 11.2)	68.5 (± 11.7)	68.1 (± 14.9)	71.4 (± 11.3)
Week 2: (Creatinine) (N=44,31,17,52,52)	0.8 (± 7.2)	-0.2 (± 8.9)	2.9 (± 9.7)	0.7 (± 6.5)
Week 4: (Creatinine) (N=45,31,17,51,48)	-0.9 (± 6.0)	0.6 (± 8.1)	2.7 (± 9.8)	1.9 (± 7.8)
Week 8: (Creatinine) (N=41,30,14,50,43)	1.0 (± 6.3)	-1.0 (± 7.8)	4.8 (± 5.3)	0.6 (± 7.8)

Week 12: (Creatinine) (N=44,30,16,49,44)	0.7 (± 8.9)	2.1 (± 7.7)	4.2 (± 11.2)	-0.5 (± 7.4)
Week 16: (Creatinine) (N=43,30,16,51,45)	0.1 (± 7.6)	1.5 (± 6.9)	6.5 (± 8.5)	-0.9 (± 8.2)
Baseline (Bilirubin) (N=47,31,17,52,52)	9.1 (± 4.1)	8.4 (± 2.9)	8.9 (± 3.1)	9.6 (± 5.0)
Week 2: (Bilirubin) (N=44,31,17,51,51)	-0.5 (± 2.2)	0.1 (± 2.2)	1.4 (± 2.0)	1.1 (± 3.3)
Week 4: (Bilirubin) (N=45,31,17,51,48)	-0.2 (± 2.6)	0.4 (± 2.7)	2.3 (± 2.8)	1.0 (± 3.3)
Week 8: (Bilirubin) (N=41,30,14,50,43)	-0.1 (± 2.8)	0.1 (± 2.1)	1.8 (± 2.1)	0.3 (± 3.1)
Week 12: (Bilirubin) (N=44,30,16,49,44)	-0.1 (± 2.4)	0.7 (± 2.4)	0.8 (± 2.7)	-0.2 (± 3.8)
Week 16: (Bilirubin) (N=43,30,16,51,45)	0.2 (± 2.4)	-0.3 (± 3.4)	0.8 (± 2.8)	-0.8 (± 3.7)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: umol/L				
arithmetic mean (standard deviation)				
Baseline (Creatinine) (N=47,31,17,52,52)	70.1 (± 11.9)			
Week 2: (Creatinine) (N=44,31,17,52,52)	0.6 (± 7.0)			
Week 4: (Creatinine) (N=45,31,17,51,48)	0.2 (± 7.8)			
Week 8: (Creatinine) (N=41,30,14,50,43)	0.5 (± 9.0)			
Week 12: (Creatinine) (N=44,30,16,49,44)	-2.8 (± 8.0)			
Week 16: (Creatinine) (N=43,30,16,51,45)	-0.2 (± 12.9)			
Baseline (Bilirubin) (N=47,31,17,52,52)	8.1 (± 2.8)			
Week 2: (Bilirubin) (N=44,31,17,51,51)	1.7 (± 2.5)			
Week 4: (Bilirubin) (N=45,31,17,51,48)	1.3 (± 3.0)			
Week 8: (Bilirubin) (N=41,30,14,50,43)	0.9 (± 2.6)			
Week 12: (Bilirubin) (N=44,30,16,49,44)	1.0 (± 2.7)			
Week 16: (Bilirubin) (N=43,30,16,51,45)	-0.4 (± 2.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Creatinine Kinase, Alkaline Phosphatase, Aspartate Aminotransferase (ASAT), Alanine Aminotransferase (ALAT) and Gamma Glutamyl Transferase (GGT)

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Creatinine Kinase, Alkaline Phosphatase, Aspartate Aminotransferase (ASAT), Alanine Aminotransferase (ALAT) and Gamma Glutamyl
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End point description:

Blood samples for clinical chemistry assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: U/L				
arithmetic mean (standard deviation)				
Baseline (Creatine Kinase) (N=47,31,17,52,52)	102.5 (± 117.2)	91.6 (± 55.6)	104.2 (± 62.9)	161.8 (± 291.4)
Week 2: (Creatine Kinase) (N=44,31,17,51,51)	28.2 (± 161.8)	7.1 (± 45.5)	8.7 (± 59.6)	-39.2 (± 280.5)
Week 4: (Creatine Kinase) (N=45,31,17,51,48)	-1.3 (± 36.8)	2.7 (± 23.4)	4.3 (± 44.2)	-30.2 (± 293.1)
Week 8: (Creatine Kinase) (N=41,30,14,50,43)	15.5 (± 106.6)	30.6 (± 127.3)	158.1 (± 580.1)	-36.9 (± 275.8)
Week 12: (Creatine Kinase) (N=44,30,16,49,44)	7.2 (± 49.7)	16.1 (± 44.7)	11.7 (± 116.5)	-13.3 (± 77.4)
Week 16: (Creatine Kinase) (N=43,30,16,51,45)	7.3 (± 37.3)	3.2 (± 34.3)	5.6 (± 54.8)	-48.8 (± 267.0)
Baseline (Alkaline Phosphatase) (N=47,31,17,52,52)	79.8 (± 24.1)	85.9 (± 18.4)	80.6 (± 19.4)	91.3 (± 43.4)
Week 2: (Alkaline Phosphatase) (N=44,31,17,51,51)	-1.5 (± 8.4)	-1.9 (± 14.6)	-2.2 (± 6.3)	-2.5 (± 6.7)
Week 4: (Alkaline Phosphatase) (N=45,31,17,51,48)	-1.1 (± 6.1)	-5.2 (± 8.6)	3.2 (± 13.1)	-3.8 (± 8.1)
Week 8: (Alkaline Phosphatase) (N=41,30,14,50,43)	-2.0 (± 8.5)	-5.0 (± 10.8)	-1.0 (± 6.2)	-5.1 (± 10.8)
Week 12: (Alkaline Phosphatase) (N=44,30,16,49,44)	-0.5 (± 8.2)	-3.2 (± 8.9)	0.2 (± 11.5)	-4.4 (± 11.8)
Week 16: (Alkaline Phosphatase) (N=43,30,16,51,45)	-0.1 (± 8.5)	-0.6 (± 14.2)	-4.9 (± 10.4)	-0.1 (± 9.6)
Baseline (ASAT) (N=47,31,17,52,52)	24.7 (± 6.0)	24.4 (± 6.5)	24.4 (± 5.1)	24.8 (± 8.0)
Week 2: (ASAT) (N=44,31,17,51,51)	0.9 (± 7.1)	0.0 (± 4.0)	0.1 (± 4.2)	-2.0 (± 7.6)
Week 4: (ASAT) (N=45,31,17,51,48)	1.5 (± 6.3)	-0.2 (± 3.8)	4.6 (± 17.7)	-1.8 (± 6.7)
Week 8: (ASAT) (N=41,30,14,50,43)	-1.3 (± 5.0)	-0.5 (± 4.7)	3.4 (± 24.2)	-1.8 (± 6.9)
Week 12: (ASAT) (N=44,30,16,49,44)	-1.1 (± 4.3)	0.3 (± 3.5)	0.9 (± 8.1)	-1.8 (± 4.7)
Week 16: (ASAT) (N=43,30,16,51,45)	0.7 (± 5.1)	0.9 (± 7.5)	-2.4 (± 3.6)	-0.2 (± 8.5)
Baseline (ALAT) (N=47,31,17,52,52)	27.0 (± 8.7)	24.0 (± 7.6)	23.9 (± 10.0)	24.4 (± 10.0)
Week 2: (ALAT) (N=44,31,17,51,51)	0.8 (± 10.6)	-0.1 (± 5.1)	-0.7 (± 5.6)	-2.1 (± 6.7)
Week 4: (ALAT) (N=45,31,17,51,48)	3.5 (± 11.6)	-1.0 (± 5.5)	16.4 (± 70.2)	-2.1 (± 5.3)
Week 8: (ALAT) (N=41,30,14,50,43)	-0.7 (± 6.1)	-0.3 (± 5.2)	0.6 (± 12.2)	-0.4 (± 9.2)
Week 12: (ALAT) (N=44,30,16,49,44)	-0.5 (± 7.4)	0.7 (± 6.0)	4.3 (± 21.0)	-0.6 (± 6.8)
Week 16: (ALAT) (N=43,30,16,51,45)	2.5 (± 13.1)	2.0 (± 9.1)	-3.5 (± 6.9)	3.1 (± 12.0)
Baseline (GGT) (N=47,31,17,52,52)	24.6 (± 17.4)	25.1 (± 15.0)	19.3 (± 15.3)	25.5 (± 23.2)
Week 2: (GGT) (N=44,31,17,51,51)	-0.2 (± 11.3)	0.0 (± 7.1)	-1.9 (± 6.7)	-2.7 (± 8.4)

Week 4: (GGT) (N=45,31,17,51,48)	3.0 (± 14.8)	-0.6 (± 9.1)	3.6 (± 14.7)	-3.5 (± 10.6)
Week 8: (GGT) (N=41,30,14,50,43)	-1.5 (± 6.4)	0.1 (± 9.2)	0.6 (± 5.9)	-2.8 (± 13.6)
Week 12: (GGT) (N=44,30,16,49,44)	-1.2 (± 10.7)	1.5 (± 9.8)	4.8 (± 13.2)	-3.0 (± 14.3)
Week 16: (GGTI Transferase) (N=43,30,16,51,45)	-0.7 (± 8.8)	2.2 (± 10.1)	1.8 (± 14.4)	-0.7 (± 10.1)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: U/L				
arithmetic mean (standard deviation)				
Baseline (Creatine Kinase) (N=47,31,17,52,52)	139.8 (± 159.3)			
Week 2: (Creatine Kinase) (N=44,31,17,51,51)	-44.3 (± 154.1)			
Week 4: (Creatine Kinase) (N=45,31,17,51,48)	-40.1 (± 163.0)			
Week 8: (Creatine Kinase) (N=41,30,14,50,43)	4.0 (± 76.1)			
Week 12: (Creatine Kinase) (N=44,30,16,49,44)	-40.3 (± 174.5)			
Week 16: (Creatine Kinase) (N=43,30,16,51,45)	-44.1 (± 172.2)			
Baseline (Alkaline Phosphatase) (N=47,31,17,52,52)	86.1 (± 25.5)			
Week 2: (Alkaline Phosphatase) (N=44,31,17,51,51)	-3.0 (± 8.2)			
Week 4: (Alkaline Phosphatase) (N=45,31,17,51,48)	-4.1 (± 8.1)			
Week 8: (Alkaline Phosphatase) (N=41,30,14,50,43)	-4.5 (± 12.0)			
Week 12: (Alkaline Phosphatase) (N=44,30,16,49,44)	-4.5 (± 8.1)			
Week 16: (Alkaline Phosphatase) (N=43,30,16,51,45)	-2.6 (± 8.0)			
Baseline (ASAT) (N=47,31,17,52,52)	24.9 (± 6.0)			
Week 2: (ASAT) (N=44,31,17,51,51)	-2.3 (± 6.1)			
Week 4: (ASAT) (N=45,31,17,51,48)	-0.3 (± 6.9)			
Week 8: (ASAT) (N=41,30,14,50,43)	-1.2 (± 5.2)			
Week 12: (ASAT) (N=44,30,16,49,44)	-2.0 (± 7.6)			
Week 16: (ASAT) (N=43,30,16,51,45)	-2.2 (± 5.3)			
Baseline (ALAT) (N=47,31,17,52,52)	25.9 (± 9.0)			
Week 2: (ALAT) (N=44,31,17,51,51)	-3.0 (± 7.6)			
Week 4: (ALAT) (N=45,31,17,51,48)	-1.1 (± 9.5)			
Week 8: (ALAT) (N=41,30,14,50,43)	-0.7 (± 10.6)			
Week 12: (ALAT) (N=44,30,16,49,44)	-1.2 (± 9.1)			
Week 16: (ALAT) (N=43,30,16,51,45)	-2.4 (± 6.7)			
Baseline (GGT) (N=47,31,17,52,52)	25.9 (± 28.0)			
Week 2: (GGT) (N=44,31,17,51,51)	-1.0 (± 7.6)			
Week 4: (GGT) (N=45,31,17,51,48)	1.4 (± 14.6)			
Week 8: (GGT) (N=41,30,14,50,43)	3.3 (± 22.6)			
Week 12: (GGT) (N=44,30,16,49,44)	1.3 (± 16.2)			

Week 16: (GGTI Transferase) (N=43,30,16,51,45)	-0.2 (± 16.4)			
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Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Protein and Albumin

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Protein and Albumin
End point description: Blood samples for clinical chemistry assessment were collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.	
End point type	Secondary
End point timeframe: From baseline to Weeks 2, 4, 8, 12 and 16	

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: g/L				
arithmetic mean (standard deviation)				
Baseline (Protein) (N=47,31,17,52,52)	67.4 (± 4.0)	67.5 (± 4.3)	66.5 (± 5.1)	67.7 (± 4.3)
Week 2: (Protein) (N=44,31,17,51,51)	-1.7 (± 2.9)	-2.1 (± 4.6)	-0.4 (± 3.7)	-1.5 (± 2.9)
Week 4: (Protein) (N=45,31,17,51,43)	-1.8 (± 3.0)	-1.5 (± 4.1)	0.2 (± 3.3)	-1.6 (± 2.7)
Week 8: (Protein) (N=41,30,14,50,43)	-1.5 (± 3.4)	-2.3 (± 4.2)	1.7 (± 4.2)	-2.0 (± 3.8)
Week 12: (Protein) (N=44,30,16,49,44)	-1.5 (± 3.0)	-1.5 (± 3.9)	-0.7 (± 4.6)	-1.7 (± 3.4)
Week 16: (Protein) (N=43,30,16,51,45)	-1.0 (± 3.2)	-1.6 (± 4.1)	-1.9 (± 5.0)	-1.8 (± 3.7)
Baseline (Albumin) (N=47,31,17,52,52)	44.7 (± 2.1)	44.9 (± 2.8)	43.6 (± 2.4)	45.2 (± 2.4)
Week 2: (Albumin) (N=44,31,17,51,51)	-1.3 (± 1.9)	-1.4 (± 2.6)	-0.1 (± 2.4)	-0.9 (± 1.8)
Week 4: (Albumin) (N=45,31,17,51,43)	-0.9 (± 2.1)	-1.0 (± 2.3)	0.5 (± 2.2)	-0.8 (± 1.9)
Week 8: (Albumin) (N=41,30,14,50,43)	-0.8 (± 2.2)	-1.2 (± 2.7)	-0.9 (± 2.5)	-0.8 (± 2.6)
Week 12: (Albumin) (N=44,30,16,49,44)	-0.6 (± 1.9)	-0.7 (± 2.1)	0.3 (± 2.6)	-0.6 (± 2.5)
Week 16: (Albumin) (N=43,30,16,51,45)	0.0 (± 2.0)	-0.4 (± 2.0)	0.1 (± 3.1)	-0.6 (± 2.3)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			

Units: g/L				
arithmetic mean (standard deviation)				
Baseline (Protein) (N=47,31,17,52,52)	67.0 (± 4.7)			
Week 2: (Protein) (N=44,31,17,51,51)	-2.1 (± 3.7)			
Week 4: (Protein) (N=45,31,17,51,43)	-1.5 (± 3.5)			
Week 8: (Protein) (N=41,30,14,50,43)	-2.4 (± 3.3)			
Week 12: (Protein) (N=44,30,16,49,44)	-1.8 (± 3.2)			
Week 16: (Protein) (N=43,30,16,51,45)	-1.7 (± 4.0)			
Baseline (Albumin) (N=47,31,17,52,52)	44.2 (± 3.0)			
Week 2: (Albumin) (N=44,31,17,51,51)	-1.3 (± 2.4)			
Week 4: (Albumin) (N=45,31,17,51,43)	-0.7 (± 2.6)			
Week 8: (Albumin) (N=41,30,14,50,43)	-1.3 (± 2.2)			
Week 12: (Albumin) (N=44,30,16,49,44)	-0.7 (± 2.2)			
Week 16: (Albumin) (N=43,30,16,51,45)	-0.4 (± 2.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Hemoglobin A1C

End point title	Change from baseline at Weeks 2, 4, 8, 12 and 16 in clinical laboratory parameters Biochemistry: Hemoglobin A1C
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End point description:

Blood samples for clinical chemistry assessment were collected and sent to the central laboratory for analysis.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 8, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: mmol/mol				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	39.22 (± 8.09)	39.05 (± 5.82)	35.84 (± 3.39)	38.78 (± 5.65)
Week 2: Change from baseline (N=44,31,17,52,51)	-0.42 (± 1.46)	0.04 (± 1.18)	0.19 (± 1.46)	-0.08 (± 1.35)
Week 4: Change from baseline (N=45,31,17,51,48)	-0.29 (± 1.91)	0.00 (± 1.96)	0.06 (± 1.47)	-0.02 (± 1.55)
Week 8: Change from baseline (N=41,30,14,49,43)	-4.0 (± 2.38)	0.26 (± 2.16)	0.62 (± 2.13)	-0.13 (± 1.72)
Week 12: Change from baseline (N=44,30,16,50,44)	0.07 (± 1.96)	0.84 (± 3.01)	1.57 (± 2.46)	0.55 (± 2.30)
Week 16: Change from baseline (N=43,30,16,51,39)	-0.64 (± 2.41)	0.69 (± 2.64)	1.16 (± 2.13)	-0.04 (± 2.22)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: mmol/mol				
arithmetic mean (standard deviation)				
Baseline (N=47,31,17,52,52)	40.88 (\pm 10.97)			
Week 2: Change from baseline (N=44,31,17,52,51)	-0.21 (\pm 2.32)			
Week 4: Change from baseline (N=45,31,17,51,48)	-0.43 (\pm 4.24)			
Week 8: Change from baseline (N=41,30,14,49,43)	-0.28 (\pm 5.11)			
Week 12: Change from baseline (N=44,30,16,50,44)	-0.94 (\pm 5.33)			
Week 16: Change from baseline (N=43,30,16,51,39)	-1.07 (\pm 5.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 12 and 16 in clinical laboratory parameters Bone: Bone Specific Alkaline Phosphatase (BAP) and Procollagen 1 N-Terminal Propeptide (PINP)

End point title	Change from baseline at Weeks 12 and 16 in clinical laboratory parameters Bone: Bone Specific Alkaline Phosphatase (BAP) and Procollagen 1 N-Terminal Propeptide (PINP)
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End point description:

Blood for assessment of bone turnover markers was collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: ug/L				
arithmetic mean (standard deviation)				
Baseline (BAP) (N=47,30,17,48,52)	12.17 (\pm 5.08)	13.01 (\pm 5.09)	13.94 (\pm 4.67)	13.37 (\pm 4.69)
Week 12: (BAP) (N=43,29,16,46,42)	0.48 (\pm 2.22)	0.34 (\pm 4.24)	-0.68 (\pm 3.36)	-0.43 (\pm 2.50)

Week 16: (BAP) (N=41,29,16,48,45)	0.86 (± 3.57)	1.22 (± 7.58)	-1.18 (± 2.49)	0.84 (± 3.55)
Baseline (PINP) (N=47,30,17,50,52)	58.1 (± 23.3)	68.0 (± 24.7)	67.6 (± 15.6)	68.6 (± 29.3)
Week 12: (PINP) (N=43,29,16,46,42)	5.0 (± 14.5)	0.5 (± 10.9)	-5.7 (± 15.9)	-2.1 (± 13.7)
Week 16: (PINP) (N=41,29,16,48,45)	3.6 (± 20.2)	-1.9 (± 9.7)	-0.9 (± 19.6)	-2.5 (± 15.4)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: ug/L				
arithmetic mean (standard deviation)				
Baseline (BAP) (N=47,30,17,48,52)	13.36 (± 5.83)			
Week 12: (BAP) (N=43,29,16,46,42)	-0.11 (± 2.73)			
Week 16: (BAP) (N=41,29,16,48,45)	0.48 (± 2.98)			
Baseline (PINP) (N=47,30,17,50,52)	59.5 (± 23.6)			
Week 12: (PINP) (N=43,29,16,46,42)	-0.7 (± 10.9)			
Week 16: (PINP) (N=41,29,16,48,45)	0.0 (± 11.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: pH

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: pH
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End point description:

Urine for urinalysis was collected and sent to the central laboratory for analysis. Urine pH was measured on a pH scale. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: pH				
arithmetic mean (standard deviation)				
Baseline (pH) (N=47,31,17,51,52)	6.00 (± 0.83)	6.10 (± 0.89)	6.09 (± 0.92)	6.21 (± 0.75)
Week 2: (pH) (N=44,31,17,51,51)	0.10 (± 0.70)	0.26 (± 0.90)	-0.15 (± 0.95)	-0.30 (± 0.83)
Week 4: (pH) (N=45,31,17,50,48)	-0.11 (± 0.85)	0.18 (± 1.31)	-0.09 (± 0.80)	-0.25 (± 0.83)
Week 12: (pH) (N=43,30,16,49,44)	-0.05 (± 0.89)	0.18 (± 1.06)	-0.19 (± 0.83)	-0.21 (± 0.78)

Week 16: (pH) (N=41,30,16,51,44)	0.05 (\pm 1.13)	0.00 (\pm 1.12)	-0.03 (\pm 0.90)	-0.19 (\pm 0.84)
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End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: pH				
arithmetic mean (standard deviation)				
Baseline (pH) (N=47,31,17,51,52)	6.08 (\pm 0.72)			
Week 2: (pH) (N=44,31,17,51,51)	-0.20 (\pm 0.83)			
Week 4: (pH) (N=45,31,17,50,48)	-0.09 (\pm 0.89)			
Week 12: (pH) (N=43,30,16,49,44)	-0.06 (\pm 0.79)			
Week 16: (pH) (N=41,30,16,51,44)	0.07 (\pm 1.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Specific Gravity

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Specific Gravity
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End point description:

Urine for urinalysis was collected and sent to the central laboratory for analysis. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Unitless				
arithmetic mean (standard deviation)				
Baseline (Specific Gravity) (N=47,31,17,51,52)	1.0167 (\pm 0.0063)	1.0167 (\pm 0.0083)	1.0166 (\pm 0.0063)	1.0154 (\pm 0.0064)
Week 2: (Specific Gravity) (N=44,31,17,50,52)	-0.0002 (\pm 0.0066)	-0.0011 (\pm 0.0085)	0.0001 (\pm 0.0060)	0.0005 (\pm 0.0068)
Week 4: (Specific Gravity) (N=45,31,17,50,48)	-0.0008 (\pm 0.0078)	0.0012 (\pm 0.0086)	-0.0026 (\pm 0.0063)	0.0015 (\pm 0.0067)
Week 12: (Specific Gravity) (N=43,30,16,49,44)	0.0020 (\pm 0.0068)	0.0015 (\pm 0.0102)	-0.0012 (\pm 0.0060)	0.0002 (\pm 0.0068)
Week 16: (Specific Gravity) (N=41,30,16,50,44)	0.0009 (\pm 0.0088)	0.0002 (\pm 0.0093)	-0.0011 (\pm 0.0059)	0.0020 (\pm 0.0066)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Unitless				
arithmetic mean (standard deviation)				
Baseline (Specific Gravity) (N=47,31,17,51,52)	1.0171 (\pm 0.0084)			
Week 2: (Specific Gravity) (N=44,31,17,50,52)	-0.0006 (\pm 0.0060)			
Week 4: (Specific Gravity) (N=45,31,17,50,48)	0.0003 (\pm 0.0079)			
Week 12: (Specific Gravity) (N=43,30,16,49,44)	0.0011 (\pm 0.0072)			
Week 16: (Specific Gravity) (N=41,30,16,50,44)	-0.0006 (\pm 0.0066)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Glucose, Bilirubin, Ketones, Occult Blood, Protein, Urobilinogen and Nitrite

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Glucose, Bilirubin, Ketones, Occult Blood, Protein, Urobilinogen and Nitrite
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End point description:

Urine for urinalysis was collected and sent to the central laboratory for analysis. Clinical relevance was judged by the investigator. Assessment was done using standard laboratory practice. For evaluation of the chemical properties of the urine sample test strips were used which have test pads of chemicals that change color when they come in contact with reagents. The degree of color change correlates with the amount of reagent present. Each color block represents a range of values. Range and direction of scores for reagents nitrite and urobilinogen: negative = normal; positive = abnormal. Range and direction of scores for all other reagents tested: negative = normal; trace, 1+, 2+, 3+ = abnormal, the higher the value, the higher the concentration of the reagent tested. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	31	17	52
Units: Participants				
number (not applicable)				
Baseline (Glucose): Negative (N=47,31,17,52,52)	46	30	17	49
Baseline (Glucose): Trace (N=47,31,17,52,52)	1	0	0	0
Baseline (Glucose): 1+ (N=47,31,17,52,52)	0	1	0	0
Baseline (Glucose): 2+ (N=47,31,17,52,52)	0	0	0	0
Baseline (Glucose): 3+ (N=47,31,17,52,52)	0	0	0	0
Week 2 (Glucose): Negative (N=44,31,17,52,51)	44	31	17	52
Week 2 (Glucose): Trace (N=44,31,17,52,51)	0	0	0	0
Week 2 (Glucose): 1+ (N=44,31,17,52,51)	0	0	0	0
Week 2 (Glucose): 2+ (N=44,31,17,52,51)	0	0	0	0
Week 2 (Glucose): 3+ (N=44,31,17,52,51)	0	0	0	0
Week 4 (Glucose): Negative (N=45,31,17,51,48)	45	30	17	51
Week 4 (Glucose): Trace (N=45,31,17,51,48)	0	1	0	0
Week 4 (Glucose): 1+ (N=45,31,17,51,48)	0	0	0	0
Week 4 (Glucose): 2+ (N=45,31,17,51,48)	0	0	0	0
Week 4 (Glucose): 3+ (N=45,31,17,51,48)	0	0	0	1
Week 12 (Glucose): Negative (N=43,30,16,49,44)	43	30	16	47
Week 12 (Glucose): Trace (N=43,30,16,49,44)	0	0	0	1
Week 12 (Glucose): 1+ (N=43,30,16,49,44)	0	0	0	0
Week 12 (Glucose): 2+ (N=43,30,16,49,44)	0	0	0	0
Week 12 (Glucose): 3+ (N=43,30,16,49,44)	0	0	0	1
Week 16 (Glucose): Negative (N=41,30,16,51,44)	40	29	16	50
Week 16 (Glucose): Trace (N=41,30,16,51,44)	0	1	0	0
Week 16 (Glucose): 1+ (N=41,30,16,51,44)	1	0	0	0
Week 16 (Glucose): 2+ (N=41,30,16,51,44)	0	0	0	0
Week 16 (Glucose): 3+ (N=41,30,16,51,44)	0	0	0	1
Baseline (Bilirubin): Negative (N=47,31,17,49,51)	47	31	17	49
Baseline (Bilirubin): 1+ (N=47,31,17,49,51)	0	0	0	0

Week 2 (Bilirubin): Negative (N=44,31,17,52,51)	44	31	17	52
Week 2 (Bilirubin): 1+ (N=44,31,17,52,51)	0	0	0	0
Week 4 (Bilirubin): Negative (N=45,31,17,51,48)	45	31	17	51
Week 4 (Bilirubin): 1+ (N=45,31,17,51,48)	0	0	0	0
Week 12 (Bilirubin): Negative (N=43,30,16,49,44)	43	30	16	49
Week 12 (Bilirubin): 1+ (N=43,30,16,49,44)	0	0	0	0
Week 16 (Bilirubin): Negative (N=41,30,16,51,44)	41	29	16	51
Week 16 (Bilirubin): 1+ (N=41,30,16,51,44)	0	1	0	0
Baseline (Ketones): Negative (N=47,31,17,49,51)	46	31	17	48
Baseline (Ketones): Trace (N=47,31,17,49,51)	1	0	0	1
Week 2 (Ketones): Negative N=44,31,17,52,51)	44	31	17	51
Week 2 (Ketones): Trace N=44,31,17,52,51)	0	0	0	1
Week 4 (Ketones): Negative (N=45,31,17,51,48)	45	31	17	50
Week 4 (Ketones): Trace (N=45,31,17,51,48)	0	0	0	1
Week 12 (Ketones): Negative (N=43,30,16,49,44)	42	30	16	48
Week 12 (Ketones): Trace (N=43,30,16,49,44)	1	0	0	1
Week 16 (Ketones): Negative	41	30	16	50
Week 16 (Ketones): Trace (N=41,30,16,51,44)	0	0	0	1
Baseline Occult Blood: Negative N=47,31,17,49,51	46	28	15	42
Baseline Occult Blood: Trace N=47,31,17,49,51	0	3	1	3
Baseline Occult Blood: 1+ N=47,31,17,49,51	1	0	0	3
Baseline Occult Blood: 2+ N=47,31,17,49,51	0	0	0	1
Baseline Occult Blood: 3+ N=47,31,17,49,51	0	0	1	0
Week 2 Occult Blood: Negative N=44,31,17,52,51	42	29	17	45
Week 2 Occult Blood: Trace N=44,31,17,52,51	1	2	0	1
Week 2 Occult Blood: 1+ N=44,31,17,52,51	1	0	0	5
Week 2 Occult Blood: 2+ N=44,31,17,52,51	0	0	0	1
Week 2 Occult Blood: 3+ N=44,31,17,52,51	0	0	0	0
Week 4 Occult Blood: Negative N=45,31,17,51,48	43	28	17	42
Week 4 Occult Blood: Trace N=45,31,17,51,48	2	1	0	5
Week 4 Occult Blood: 1+ N=45,31,17,51,48	0	2	0	3

Week 4 Occult Blood: 2+ N=45,31,17,51,48	0	0	0	0
Week 4 Occult Blood: 3+ N=45,31,17,51,48	0	0	0	1
Week 12 Occult Blood: Negative N=43,30,16,49,44	40	30	13	40
Week 12 Occult Blood: Trace N=43,30,16,49,44	1	0	1	5
Week 12 Occult Blood: 1+ N=43,30,16,49,44	2	0	1	3
Week 12 Occult Blood: 2+ N=43,30,16,49,44	0	0	1	1
Week 12 Occult Blood: 3+ N=43,30,16,49,44	0	0	0	0
Week 16 Occult Blood: Negative N=41,30,16,51,44	38	27	14	45
Week 16 Occult Blood: Trace N=41,30,16,51,44	2	3	1	3
Week 16 Occult Blood: 1+ N=41,30,16,51,44	0	0	0	3
Week 16 Occult Blood: 2+ N=41,30,16,51,44	1	0	0	0
Week 16 Occult Blood: 3+ N=41,30,16,51,44	0	0	1	0
Baseline Protein: Negative N=47,31,17,49,51	45	31	16	48
Baseline Protein: Trace N=47,31,17,49,51	2	0	1	1
Baseline Protein: 1+ N=47,31,17,49,51	0	0	0	0
Baseline Protein: 2+ N=47,31,17,49,51	0	0	0	0
Baseline Protein: 3+ N=47,31,17,49,51	0	0	0	0
Week 2 Protein: Negative N=44,31,17,52,51	44	31	17	52
Week 2 Protein: Trace N=44,31,17,52,51	0	0	0	0
Week 2 Protein: 1+ N=44,31,17,52,51	0	0	0	0
Week 2 Protein: 2+ N=44,31,17,52,51	0	0	0	0
Week 2 Protein: 3+ N=44,31,17,52,51	0	0	0	0
Week 4 Protein: Negative N=45,31,17,51,48	44	31	17	49
Week 4 Protein: Trace N=45,31,17,51,48	0	0	0	2
Week 4 Protein: 1+ N=45,31,17,51,48	1	0	00	0
Week 4 Protein: 2+ N=45,31,17,51,48	0	0	0	0
Week 4 Protein: 3+ N=45,31,17,51,48	0	0	0	0
Week 12 Protein: Negative N=43,30,16,49,44	41	30	14	47
Week 12 Protein: Trace N=43,30,16,49,44	1	0	0	1
Week 12 Protein: 1+ N=43,30,16,49,44	1	0	2	1
Week 12 (Protein): 2+ (N=43,30,16,49,44)	0	0	0	0
Week 12 (Protein): 3+ (N=43,30,16,49,44)	0	0	0	0
Week 16 (Protein): Negative (N=41,30,16,51,44)	39	30	15	50
Week 16 (Protein): Trace (N=41,30,16,51,44)	1	0	0	0
Week 16 (Protein): 1+ (N=41,30,16,51,44)	0	0	0	1

Week 16 (Protein): 2+ (N=41,30,16,51,44)	0	0	1	0
Week 16 (Protein): 3+ (N=41,30,16,51,44)	1	0	0	0
Baseline Urobilinogen: Negative N=47,31,17,49,51	47	31	17	49
Week 2 Urobilinogen: Negative N=44,31,17,52,51	44	31	17	52
Week 4 Urobilinogen: Negative N=45,31,17,51,48	45	31	17	51
Week 12 Urobilinogen: Negative N=43,30,16,49,44	43	30	16	49
Week 16 Urobilinogen: Negative N=41,30,16,51,44	41	30	16	51
Baseline (Nitrite): Negative (N=47,31,17,49,51)	47	29	17	48
Baseline (Nitrite): Positive (N=47,31,17,49,51)	0	2	0	1
Week 2 (Nitrite): Negative (N=44,31,17,52,51)	44	29	17	51
Week 2 (Nitrite): Positive (N=44,31,17,52,51)	0	2	0	1
Week 4 (Nitrite): Negative (N=45,31,17,51,48)	45	29	17	50
Week 4 (Nitrite): Positive (N=45,31,17,51,48)	0	2	0	1
Week 12 (Nitrite): Negative (N=43,30,16,49,44)	42	29	16	49
Week 12 (Nitrite): Positive (N=43,30,16,49,44)	1	1	0	0
Week 16 (Nitrite): Negative (N=41,30,16,51,44)	41	30	16	51
Week 16 (Nitrite): Positive (N=41,30,16,51,44)	0	0	0	0

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Participants				
number (not applicable)				
Baseline (Glucose): Negative (N=47,31,17,52,52)	48			
Baseline (Glucose): Trace (N=47,31,17,52,52)	1			
Baseline (Glucose): 1+ (N=47,31,17,52,52)	0			
Baseline (Glucose): 2+ (N=47,31,17,52,52)	0			
Baseline (Glucose): 3+ (N=47,31,17,52,52)	2			
Week 2 (Glucose): Negative (N=44,31,17,52,51)	49			
Week 2 (Glucose): Trace (N=44,31,17,52,51)	0			
Week 2 (Glucose): 1+ (N=44,31,17,52,51)	1			

Week 2 (Glucose): 2+ (N=44,31,17,52,51)	0			
Week 2 (Glucose): 3+ (N=44,31,17,52,51)	1			
Week 4 (Glucose): Negative (N=45,31,17,51,48)	46			
Week 4 (Glucose): Trace (N=45,31,17,51,48)	0			
Week 4 (Glucose): 1+ (N=45,31,17,51,48)	0			
Week 4 (Glucose): 2+ (N=45,31,17,51,48)	0			
Week 4 (Glucose): 3+ (N=45,31,17,51,48)	2			
Week 12 (Glucose): Negative (N=43,30,16,49,44)	40			
Week 12 (Glucose): Trace (N=43,30,16,49,44)	1			
Week 12 (Glucose): 1+ (N=43,30,16,49,44)	1			
Week 12 (Glucose): 2+ (N=43,30,16,49,44)	0			
Week 12 (Glucose): 3+ (N=43,30,16,49,44)	2			
Week 16 (Glucose): Negative (N=41,30,16,51,44)	43			
Week 16 (Glucose): Trace (N=41,30,16,51,44)	0			
Week 16 (Glucose): 1+ (N=41,30,16,51,44)	0			
Week 16 (Glucose): 2+ (N=41,30,16,51,44)	0			
Week 16 (Glucose): 3+ (N=41,30,16,51,44)	1			
Baseline (Bilirubin): Negative (N=47,31,17,49,51)	51			
Baseline (Bilirubin): 1+ (N=47,31,17,49,51)	0			
Week 2 (Bilirubin): Negative (N=44,31,17,52,51)	51			
Week 2 (Bilirubin): 1+ (N=44,31,17,52,51)	0			
Week 4 (Bilirubin): Negative (N=45,31,17,51,48)	48			
Week 4 (Bilirubin): 1+ (N=45,31,17,51,48)	0			
Week 12 (Bilirubin): Negative (N=43,30,16,49,44)	44			
Week 12 (Bilirubin): 1+ (N=43,30,16,49,44)	0			
Week 16 (Bilirubin): Negative (N=41,30,16,51,44)	44			
Week 16 (Bilirubin): 1+ (N=41,30,16,51,44)	0			
Baseline (Ketones): Negative (N=47,31,17,49,51)	50			
Baseline (Ketones): Trace (N=47,31,17,49,51)	1			
Week 2 (Ketones): Negative N=44,31,17,52,51)	50			
Week 2 (Ketones): Trace N=44,31,17,52,51)	1			

Week 4 (Ketones): Negative (N=45,31,17,51,48)	48			
Week 4 (Ketones): Trace (N=45,31,17,51,48)	0			
Week 12 (Ketones): Negative (N=43,30,16,49,44)	43			
Week 12 (Ketones): Trace (N=43,30,16,49,44)	1			
Week 16 (Ketones): Negative	44			
Week 16 (Ketones): Trace (N=41,30,16,51,44)	0			
Baseline Occult Blood: Negative N=47,31,17,49,51	47			
Baseline Occult Blood: Trace N=47,31,17,49,51	4			
Baseline Occult Blood: 1+ N=47,31,17,49,51	0			
Baseline Occult Blood: 2+ N=47,31,17,49,51	0			
Baseline Occult Blood: 3+ N=47,31,17,49,51	0			
Week 2 Occult Blood: Negative N=44,31,17,52,51	47			
Week 2 Occult Blood: Trace N=44,31,17,52,51	3			
Week 2 Occult Blood: 1+ N=44,31,17,52,51	1			
Week 2 Occult Blood: 2+ N=44,31,17,52,51	0			
Week 2 Occult Blood: 3+ N=44,31,17,52,51	0			
Week 4 Occult Blood: Negative N=45,31,17,51,48	47			
Week 4 Occult Blood: Trace N=45,31,17,51,48	1			
Week 4 Occult Blood: 1+ N=45,31,17,51,48	0			
Week 4 Occult Blood: 2+ N=45,31,17,51,48	0			
Week 4 Occult Blood: 3+ N=45,31,17,51,48	0			
Week 12 Occult Blood: Negative N=43,30,16,49,44	42			
Week 12 Occult Blood: Trace N=43,30,16,49,44	2			
Week 12 Occult Blood: 1+ N=43,30,16,49,44	0			
Week 12 Occult Blood: 2+ N=43,30,16,49,44	0			
Week 12 Occult Blood: 3+ N=43,30,16,49,44	0			
Week 16 Occult Blood: Negative N=41,30,16,51,44	39			
Week 16 Occult Blood: Trace N=41,30,16,51,44	4			
Week 16 Occult Blood: 1+ N=41,30,16,51,44	1			
Week 16 Occult Blood: 2+ N=41,30,16,51,44	0			
Week 16 Occult Blood: 3+ N=41,30,16,51,44	0			

Baseline Protein: Negative N=47,31,17,49,51	49			
Baseline Protein: Trace N=47,31,17,49,51	1			
Baseline Protein: 1+ N=47,31,17,49,51	1			
Baseline Protein: 2+ N=47,31,17,49,51	0			
Baseline Protein: 3+ N=47,31,17,49,51	0			
Week 2 Protein: Negative N=44,31,17,52,51	49			
Week 2 Protein: Trace N=44,31,17,52,51	0			
Week 2 Protein: 1+ N=44,31,17,52,51	0			
Week 2 Protein: 2+ N=44,31,17,52,51	2			
Week 2 Protein: 3+ N=44,31,17,52,51	0			
Week 4 Protein: Negative N=45,31,17,51,48	45			
Week 4 Protein: Trace N=45,31,17,51,48	3			
Week 4 Protein: 1+ N=45,31,17,51,48	0			
Week 4 Protein: 2+ N=45,31,17,51,48	0			
Week 4 Protein: 3+ N=45,31,17,51,48	0			
Week 12 Protein: Negative N=43,30,16,49,44	43			
Week 12 Protein: Trace N=43,30,16,49,44	1			
Week 12 Protein: 1+ N=43,30,16,49,44	0			
Week 12 (Protein): 2+ (N=43,30,16,49,44)	0			
Week 12 (Protein): 3+ (N=43,30,16,49,44)	0			
Week 16 (Protein): Negative (N=41,30,16,51,44)	43			
Week 16 (Protein): Trace (N=41,30,16,51,44)	1			
Week 16 (Protein): 1+ (N=41,30,16,51,44)	0			
Week 16 (Protein): 2+ (N=41,30,16,51,44)	0			
Week 16 (Protein): 3+ (N=41,30,16,51,44)	0			
Baseline Urobilinogen: Negative N=47,31,17,49,51	51			
Week 2 Urobilinogen: Negative N=44,31,17,52,51	51			
Week 4 Urobilinogen: Negative N=45,31,17,51,48	48			
Week 12 Urobilinogen: Negative N=43,30,16,49,44	44			
Week 16 Urobilinogen: Negative N=41,30,16,51,44	44			
Baseline (Nitrite): Negative (N=47,31,17,49,51)	48			
Baseline (Nitrite): Positive (N=47,31,17,49,51)	3			
Week 2 (Nitrite): Negative (N=44,31,17,52,51)	47			
Week 2 (Nitrite): Positive (N=44,31,17,52,51)	4			
Week 4 (Nitrite): Negative (N=45,31,17,51,48)	47			

Week 4 (Nitrite): Positive (N=45,31,17,51,48)	1			
Week 12 (Nitrite): Negative (N=43,30,16,49,44)	42			
Week 12 (Nitrite): Positive (N=43,30,16,49,44)	2			
Week 16 (Nitrite): Negative (N=41,30,16,51,44)	42			
Week 16 (Nitrite): Positive (N=41,30,16,51,44)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Erythrocytes and Leukocytes

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Erythrocytes and Leukocytes
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End point description:

Urine for urinalysis was collected and sent to the central laboratory for analysis. Results are reported according to the amount present in the microscope's field of view at high magnification (/HPF [high-power field]). In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	12	7	23
Units: cells/HPF				
arithmetic mean (standard deviation)				
Baseline (Erythrocytes (/HPF)) (N=18,12,7,23,23)	1.3 (± 1.5)	0.8 (± 1.1)	2.0 (± 2.6)	1.5 (± 2.4)
Week 2: (Erythrocytes (/HPF)) (N=7,5,2,9,14)	-0.6 (± 2.6)	-0.6 (± 0.5)	-1.0 (± 1.4)	-0.8 (± 4.0)
Week 4: (Erythrocytes (/HPF)) (N=9,4,3,13,9)	-0.1 (± 1.6)	0.5 (± 1.3)	-2.7 (± 3.1)	-0.5 (± 3.1)
Week 12: (Erythrocytes (/HPF)) (N=8,7,5,11,11)	-0.4 (± 2.2)	-0.4 (± 0.8)	0.4 (± 0.5)	1.4 (± 3.7)
Week 16: (Erythrocytes (/HPF)) (N=10,3,4,8,9)	-0.3 (± 2.1)	-0.7 (± 1.2)	-1.5 (± 2.4)	0.3 (± 2.1)
Baseline (Leukocytes (/HPF)) (N=18,12,7,22,23)	9.5 (± 16.2)	2.6 (± 4.3)	1.6 (± 1.7)	5.3 (± 11.9)
Week 2: (Leukocytes (/HPF)) (N=7,5,2,8,14)	-6.7 (± 15.9)	0.0 (± 3.6)	0.5 (± 2.1)	-1.0 (± 2.7)
Week 4: (Leukocytes (/HPF)) (N=9,3,3,12,9)	-6.0 (± 20.9)	1.0 (± 1.0)	6.3 (± 11.8)	0.3 (± 4.1)
Week 12: (Leukocytes (/HPF)) (N=8,6,5,10,11)	6.4 (± 47.9)	3.5 (± 6.7)	0.6 (± 3.0)	0.6 (± 2.3)

Week 16: (Leukocytes (/HPF)) (N=10,3,4,8,9)	-7.6 (± 21.9)	3.0 (± 4.4)	3.0 (± 4.2)	0.6 (± 1.3)
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End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: cells/HPF				
arithmetic mean (standard deviation)				
Baseline (Erythrocytes (/HPF)) (N=18,12,7,23,23)	0.6 (± 0.7)			
Week 2: (Erythrocytes (/HPF)) (N=7,5,2,9,14)	0.9 (± 3.0)			
Week 4: (Erythrocytes (/HPF)) (N=9,4,3,13,9)	0.3 (± 1.1)			
Week 12: (Erythrocytes (/HPF)) (N=8,7,5,11,11)	0.2 (± 1.5)			
Week 16: (Erythrocytes (/HPF)) (N=10,3,4,8,9)	0.1 (± 0.3)			
Baseline (Leukocytes (/HPF)) (N=18,12,7,22,23)	3.0 (± 5.8)			
Week 2: (Leukocytes (/HPF)) (N=7,5,2,8,14)	-0.4 (± 6.4)			
Week 4: (Leukocytes (/HPF)) (N=9,3,3,12,9)	0.8 (± 5.8)			
Week 12: (Leukocytes (/HPF)) (N=8,6,5,10,11)	-1.5 (± 5.1)			
Week 16: (Leukocytes (/HPF)) (N=10,3,4,8,9)	13.3 (± 33.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Hyaline Casts

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Hyaline Casts
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End point description:

Urine for urinalysis was collected and sent to the central laboratory for analysis. Results are reported according to the amount present in the microscope's field of view at low magnification (/LPF [low-power field]). In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively. From week 2 on, all numbers are changes from baseline.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	12	7	23
Units: cells/LPF				
arithmetic mean (standard deviation)				
Baseline (Hyaline Casts (/LPF)) (N=18,12,7,23,23)	1.9 (± 2.0)	0.8 (± 1.6)	0.1 (± 0.4)	0.8 (± 1.4)
Week 2: (Hyaline Casts (/LPF)) (N=7,5,2,9,14)	-1.1 (± 2.7)	-0.6 (± 1.5)	0.0 (± 0.0)	-0.1 (± 0.6)
Week 4: (Hyaline Casts (/LPF)) (N=9,4,3,13,9)	-0.2 (± 3.6)	-0.5 (± 1.0)	5.3 (± 6.8)	0.3 (± 1.8)
Week 12: (Hyaline Casts (/LPF)) (N=8,7,5,11,11)	-0.3 (± 2.8)	-0.1 (± 1.5)	2.2 (± 4.4)	-0.3 (± 0.8)
Week 16: (Hyaline Casts (/LPF)) (N=10,3,4,8,9)	-1.2 (± 2.9)	0.7 (± 1.2)	0.5 (± 1.0)	0.1 (± 0.8)

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: cells/LPF				
arithmetic mean (standard deviation)				
Baseline (Hyaline Casts (/LPF)) (N=18,12,7,23,23)	1.7 (± 6.2)			
Week 2: (Hyaline Casts (/LPF)) (N=7,5,2,9,14)	0.1 (± 1.5)			
Week 4: (Hyaline Casts (/LPF)) (N=9,4,3,13,9)	-0.4 (± 1.7)			
Week 12: (Hyaline Casts (/LPF)) (N=8,7,5,11,11)	-2.8 (± 9.0)			
Week 16: (Hyaline Casts (/LPF)) (N=10,3,4,8,9)	-0.2 (± 0.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Bacteria, Yeast Cells, Granular Casts, RBC Casts, Waxy Casts, WBC Casts, Calcium Oxalate Crystals, Triple Phosphate (TP) Crystals and Uric Acid (UA) Crystals

End point title	Change from baseline at Weeks 2, 4, 12 and 16 in clinical laboratory parameters Urinalysis: Bacteria, Yeast Cells, Granular Casts, RBC Casts, Waxy Casts, WBC Casts, Calcium Oxalate Crystals, Triple Phosphate (TP) Crystals and Uric Acid (UA) Crystals
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End point description:

Urine for urinalysis was collected and sent to the central laboratory for analysis. The evaluation of components in the urine samples such as bacteria, yeast, red blood cells (RBC), white blood cells (WBC), casts and crystals was performed by microscopy. Results are reported according to the amount present in the microscope's field of view at low magnification (/LPF [low-power field]) and high

magnification (/HPF [high-power field]).

Range and direction of scores microscopic identification of urine components:

- Bacteria: none seen, 1+, 2+, 3+,4+, TNTC (too numerous to count).

- Other urine components: none seen=normal; few, moderate, many, TNTC = abnormal.

The higher the value, the higher the concentration of the component evaluated. In categories the number of subjects analyzed (N) for each week is mentioned for each reporting group respectively.

End point type	Secondary
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End point timeframe:

From baseline to Weeks 2, 4, 12 and 16

End point values	Placebo	40 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	120 mg Elinzanetant (BAY3427080)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	11	8	18
Units: Participants				
Baseline Bacteria(/HPF): None seen N=9,11,5,17,19	4	4	2	9
Baseline Bacteria(/HPF): 1+ N=9,11,5,17,19	4	3	1	6
Baseline Bacteria(/HPF): 2+ N=9,11,5,17,19	0	1	1	1
Baseline Bacteria(/HPF): 3+ N=9,11,5,17,19	0	1	0	0
Baseline Bacteria(/HPF): 4+ N=9,11,5,17,19	0	0	1	1
Baseline Bacteria(/HPF): TNTC N=9,11,5,17,19	1	2	0	0
Week 2 Bacteria(/HPF): None seen N=8,9,3,11,18	3	3	1	5
Week 2 Bacteria(/HPF): 1+ N=8,9,3,11,18	1	2	1	4
Week 2 Bacteria(/HPF): 2+ N=8,9,3,11,18	1	2	1	0
Week 2 Bacteria(/HPF): 3+ N=8,9,3,11,18	0	1	0	1
Week 2 Bacteria(/HPF): 4+ N=8,9,3,11,18	2	0	0	0
Week 2 Bacteria(/HPF): TNTC N=8,9,3,11,18	1	1	0	1
Week 4 Bacteria(/HPF): None seen N=11,6,3,15,13	7	3	1	9
Week 4 Bacteria(/HPF): 1+ N=11,6,3,15,13	0	0	1	1
Week 4 Bacteria(/HPF): 2+ N=11,6,3,15,13	2	0	1	4
Week 4 Bacteria(/HPF): 3+ N=11,6,3,15,13	0	0	0	0
Week 4 Bacteria(/HPF): 4+ N=11,6,3,15,13	0	0	0	0
Week 4 Bacteria(/HPF): TNTC N=11,6,3,15,13	2	3	0	1
Week 12 Bacteria(/HPF): None seen N=12,8,8,18,12	1	3	3	11
Week 12 Bacteria(/HPF): 1+ N=12,8,8,18,12	7	2	3	3
Week 12 Bacteria(/HPF): 2+ N=12,8,8,18,12	1	0	2	3

Week 12 Bacteria(/HPF): 3+ N=12,8,8,18,12	1	0	0	1
Week 12 Bacteria(/HPF): 4+ N=12,8,8,18,12)	0	1	0	0
Week 12 Bacteria(/HPF): TNTC N=12,8,8,18,12	2	2	0	0
Week 16 Bacteria(/HPF): None seen N=13,6,5,12,14	4	2	1	1
Week 16 (Bacteria(/HPF)): 1+ (N=13,6,5,12,14)	5	0	0	3
Week 16 Bacteria(/HPF): 2+ N=13,6,5,12,14	4	2	1	1
Week 16 Bacteria(/HPF): 3+ N=13,6,5,12,14	1	0	0	1
Week 16 Bacteria(/HPF): 4+ N=13,6,5,12,14	1	1	2	0
Week 16 Bacteria(/HPF): TNTC N=13,6,5,12,14	0	0	0	1
Baseline Yeast Cells HPF: None seen N=9,11,5,17,19	9	11	5	17
Baseline Yeast Cells HPF: Few N=9,11,5,17,19	0	0	0	0
Week 2 Yeast Cells HPF) None seen N=8,9,3,11,18	8	9	3	11
Week 2 (Yeast Cells(/HPF)): Few (N=8,9,3,11,18)	0	0	0	0
Week 4 Yeast Cells HPF: None seen N=11,6,3,15,13	11	6	3	15
Week 4 Yeast Cells HPF: Few N=11,6,3,15,13	0	0	0	0
Week 12 (east Cells HPF: None seen N=12,8,8,18,12	12	8	8	18
Week 12 Yeast Cells HPF: Few N=12,8,8,18,12	0	0	0	0
Week 16 Yeast Cells HPF: None seen N=13,6,5,12,14	13	6	5	12
Week 16 Yeast Cells HPF: Few N=13,6,5,12,14	0	0	0	0
BaselineGranularCastsLPF:None seen N=9,11,5,17,19	9	11	5	17
Week2:Granular CastsLPF:None seen N=8,9,3,11,18	8	9	3	11
Week4:Granular CastsLPF:None seen N=11,6,3,15,13	11	6	3	15
Week12:Granular CastsLPF:None seen N=12,8,8,18,12	12	8	8	18
Week16:Granular CastsLPF:None seen N=13,6,5,12,14	13	6	5	12
Baseline RBC Casts LPF: None seen N=9,11,5,17,19	9	11	5	17
Week 2 RBC Casts LPF: None seen N=8,9,3,11,18	8	9	3	11
Week4RBCCastsLPF: None seen N=11,6,3,15,13	11	6	3	15
Week12RBC CastsLPF: None seen N=12,8,8,18,12	12	8	8	18
Week 16 RBC CastsLPF: None seen N=13,6,5,12,14	13	6	5	12
Baseline Waxy CastsLPF: None seen N=9,11,5,17,19	9	11	5	17
Week2 Waxy Casts(LPF: None seen N=8,9,3,11,18	8	9	3	11

Week4 Waxy CastsLPF: None seen N=11,6,3,15,13	11	6	3	15
Week12 Waxy CastsLPF: None seen N=12,8,8,18,12	12	8	8	18
Week 16 Waxy CastsLPF: None seen N=13,6,5,12,14	13	6	5	12
Baseline WBC CastsLPF: None seen N=9,11,5,17,19	9	11	5	17
Week2 WBC CastsLPF: None seen N=8,9,3,11,18	8	9	3	11
Week4 WBC CastsLPF: None seen N=11,6,3,15,13	11	6	3	15
Week 12 WBC CastsLPF: None seen N=12,8,8,18,12	12	8	8	18
Week16 WBC CastsLPF: None seen N=13,6,5,12,14	13	6	5	12
Base CaC2O4CrystalsHPF: None seen N=9,11,5,17,19	8	11	5	13
Base CaC2O4CrystalsHPF: Few N=9,11,5,17,19	1	0	0	2
Base CaC2O4Crystals(/HPF: Moderate N=9,11,5,17,19	0	0	0	0
Base CaC2O4CrystalsHPF: Many N=9,11,5,17,19	0	0	0	2
Base CaC2O4CrystalsHPF: TNTC N=9,11,5,17,19	0	0	0	0
Week2 CaC2O4CrystalsHPF: None seen N=8,9,3,11,18	6	8	3	9
Week2 CaC2O4CrystalsHPF: Few N=8,9,3,11,18	2	0	0	1
Week2 CaC2O4CrystalsHPF: Moderate N=8,9,3,11,18	0	0	0	0
Week2 CaC2O4CrystalsHPF: Many N=8,9,3,11,18	0	1	0	1
Week2 CaC2O4CrystalsHPF: TNTC N=8,9,3,11,18	0	0	0	0
Week4 CaC2O4CrystalsHPF: None seen N=11,6,3,15,13	9	5	3	12
Week4 CaC2O4CrystalsHPF: Few N=11,6,3,15,13	0	0	0	1
Week 4 CaC2O4CrystalsHPF: Moderate N=11,6,3,15,13	1	1	0	1
Week4 CaC2O4CrystalsHPF: Many N=11,6,3,15,13	1	0	0	1
Week4 CaC2O4CrystalsHPF: TNTC (N=11,6,3,15,13)	0	0	0	0
Week12 CaC2O4CrystalsHPF: None seen N=12,8,8,18,12	11	7	8	16
Week12 CaC2O4CrystalsHPF: Few N=12,8,8,18,12	1	0	0	0
Week12 CaC2O4CrystalsHPF: Moderate N=12,8,8,18,12	0	1	0	1
Week12 CaC2O4CrystalsHPF: Many N=12,8,8,18,12	0	0	0	1
Week12 CaC2O4CrystalsHPF: TNTC N=12,8,8,18,12	0	0	0	0
Week16 CaC2O4CrystalsHPF: None seen N=13,6,5,12,14	10	4	5	11
Week16 CaC2O4CrystalsHPF: Few N=13,6,5,12,14	2	2	0	0
Week16 CaC2O4CrystalsHPF: Moderate N=13,6,5,12,14	1	0	0	0

Week16 CaC2O4CrystalsHPF: Many N=13,6,5,12,14	0	0	0	1
Week16 CaC2O4CrystalsHPF: TNTC N=13,6,5,12,14	0	0	0	0
Baseline TPCrystalsHPF: None seen N=9,11,5,17,19	9	11	5	17
Week2 TPCrystalsHPF: None seen N=8,9,3,11,18	8	9	3	11
Week4 TPCrystalsHPF: None seen N=11,6,3,15,13	11	6	3	15
Week12 TPCrystalsHPF: None seen N=12,8,8,18,12	12	8	8	18
Week16 TPCrystalsHPF: None seen N=13,6,5,12,14	13	6	5	12
Baseline UACrystalsHPF: None seen N=9,11,5,17,19	9	11	5	16
Baseline UACrystalsHPF: Few N=9,11,5,17,19	0	0	0	1
Baseline UACrystalsHPF: Moderate N=9,11,5,17,19	0	0	0	0
Week2 UACrystalsHPF: None seen N=8,9,3,11,18	8	9	3	11
Week2 UACrystalsHPF: Few N=8,9,3,11,18	0	0	0	0
Week2 UACrystalsHPF: Moderate N=8,9,3,11,18	0	0	0	0
Week4 UACrystalsHPF: None seen N=11,6,3,15,13	11	6	3	14
Week4 UACrystalsHPF: Few N=11,6,3,15,13	0	0	0	0
Week4 UACrystalsHPF: Moderate N=11,6,3,15,13	0	0	0	1
Week12 UACrystalsHPF: None seen N=12,8,8,18,12	11	8	8	18
Week12 UACrystalsHPF: Few N=12,8,8,18,12	1	0	0	0
Week12 UACrystalsHPF: Moderate N=12,8,8,18,12	0	0	0	0
Week16 UACrystalsHPF: None seen N=13,6,5,12,14	13	6	4	11
Week16 UACrystalsHPF: Few N=13,6,5,12,14	0	0	1	1
Week16 UACrystalsHPF: Moderate N=13,6,5,12,14	0	0	0	0

End point values	160 mg Elinzanetant (BAY3427080)			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Participants				
Baseline Bacteria(/HPF): None seen N=9,11,5,17,19	7			
Baseline Bacteria(/HPF): 1+ N=9,11,5,17,19	5			
Baseline Bacteria(/HPF): 2+ N=9,11,5,17,19	2			

Baseline Bacteria(/HPF): 3+ N=9,11,5,17,19	2			
Baseline Bacteria(/HPF): 4+ N=9,11,5,17,19	1			
Baseline Bacteria(/HPF): TNTC N=9,11,5,17,19	2			
Week 2 Bacteria(/HPF): None seen N=8,9,3,11,18	6			
Week 2 Bacteria(/HPF): 1+ N=8,9,3,11,18	4			
Week 2 Bacteria(/HPF): 2+ N=8,9,3,11,18	6			
Week 2 Bacteria(/HPF): 3+ N=8,9,3,11,18	1			
Week 2 Bacteria(/HPF): 4+ N=8,9,3,11,18	0			
Week 2 Bacteria(/HPF): TNTC N=8,9,3,11,18	1			
Week 4 Bacteria(/HPF): None seen N=11,6,3,15,13	2			
Week 4 Bacteria(/HPF): 1+ N=11,6,3,15,13	3			
Week 4 Bacteria(/HPF): 2+ N=11,6,3,15,13	3			
Week 4 Bacteria(/HPF): 3+ N=11,6,3,15,13	1			
Week 4 Bacteria(/HPF): 4+ N=11,6,3,15,13	2			
Week 4 Bacteria(/HPF): TNTC N=11,6,3,15,13	2			
Week 12 Bacteria(/HPF): None seen N=12,8,8,18,12	3			
Week 12 Bacteria(/HPF): 1+ N=12,8,8,18,12	3			
Week 12 Bacteria(/HPF): 2+ N=12,8,8,18,12	5			
Week 12 Bacteria(/HPF): 3+ N=12,8,8,18,12	0			
Week 12 Bacteria(/HPF): 4+ N=12,8,8,18,12	0			
Week 12 Bacteria(/HPF): TNTC N=12,8,8,18,12	1			
Week 16 Bacteria(/HPF): None seen N=13,6,5,12,14	1			
Week 16 Bacteria(/HPF): 1+ (N=13,6,5,12,14)	3			
Week 16 Bacteria(/HPF): 2+ N=13,6,5,12,14	1			
Week 16 Bacteria(/HPF): 3+ N=13,6,5,12,14	2			
Week 16 Bacteria(/HPF): 4+ N=13,6,5,12,14	3			
Week 16 Bacteria(/HPF): TNTC N=13,6,5,12,14	1			
Baseline Yeast Cells HPF: None seen N=9,11,5,17,19	19			
Baseline Yeast Cells HPF: Few N=9,11,5,17,19	0			
Week 2 Yeast Cells HPF) None seen N=8,9,3,11,18	17			
Week 2 (Yeast Cells(/HPF)): Few (N=8,9,3,11,18)	1			

Week 4 Yeast Cells HPF: None seen N=11,6,3,15,13	13			
Week 4 Yeast Cells HPF: Few N=11,6,3,15,13	0			
Week 12 (east Cells HPF: None seen N=12,8,8,18,12	12			
Week 12 Yeast Cells HPF: Few N=12,8,8,18,12	0			
Week 16 Yeast Cells HPF: None seen N=13,6,5,12,14	14			
Week 16 Yeast Cells HPF: Few N=13,6,5,12,14	0			
BaselineGranularCastsLPF:None seen N=9,11,5,17,19	19			
Week2:Granular CastsLPF:None seen N=8,9,3,11,18	18			
Week4:Granular CastsLPF:None seen N=11,6,3,15,13	13			
Week12:Granular CastsLPF:None seen N=12,8,8,18,12	12			
Week16:Granular CastsLPF:None seen N=13,6,5,12,14	14			
Baseline RBC Casts LPF: None seen N=9,11,5,17,19	19			
Week 2 RBC Casts LPF: None seen N=8,9,3,11,18	18			
Week4RBCCastsLPF: None seen N=11,6,3,15,13	13			
Week12RBC CastsLPF: None seen N=12,8,8,18,12	12			
Week 16 RBC CastsLPF: None seen N=13,6,5,12,14	14			
Baseline Waxy CastsLPF: None seen N=9,11,5,17,19	19			
Week2 Waxy Casts(LPF: None seen N=8,9,3,11,18	18			
Week4 Waxy CastsLPF: None seen N=11,6,3,15,13	13			
Week12 Waxy CastsLPF: None seen N=12,8,8,18,12	12			
Week 16 Waxy CastsLPF: None seen N=13,6,5,12,14	14			
Baseline WBC CastsLPF: None seen N=9,11,5,17,19	19			
Week2 WBC CastsLPF: None seen N=8,9,3,11,18	18			
Week4 WBC CastsLPF: None seen N=11,6,3,15,13	13			
Week 12 WBC CastsLPF: None seen N=12,8,8,18,12	12			
Week16 WBC CastsLPF: None seen N=13,6,5,12,14	14			
Base CaC2O4CrystalsHPF: None seen N=9,11,5,17,19	16			
Base CaC2O4CrystalsHPF: Few N=9,11,5,17,19	2			
Base CaC2O4Crystals(/HPF: Moderate N=9,11,5,17,19	1			
Base CaC2O4CrystalsHPF: Many N=9,11,5,17,19	0			
Base CaC2O4CrystalsHPF: TNTC N=9,11,5,17,19	0			

Week2 CaC2O4CrystalsHPF: None seen N=8,9,3,11,18	17			
Week2 CaC2O4CrystalsHPF: Few N=8,9,3,11,18	0			
Week2 CaC2O4CrystalsHPF: Moderate N=8,9,3,11,18	1			
Week2 CaC2O4CrystalsHPF: Many N=8,9,3,11,18	0			
Week2 CaC2O4CrystalsHPF: TNTC N=8,9,3,11,18	0			
Week4 CaC2O4CrystalsHPF: None seen N=11,6,3,15,13	10			
Week4 CaC2O4CrystalsHPF: Few N=11,6,3,15,13	1			
Week 4 CaC2O4CrystalsHPF: Moderate N=11,6,3,15,13	0			
Week4 CaC2O4CrystalsHPF: Many N=11,6,3,15,13	1			
Week4 CaC2O4CrystalsHPF: TNTC (N=11,6,3,15,13)	1			
Week12 CaC2O4CrystalsHPF: None seen N=12,8,8,18,12	11			
Week12 CaC2O4CrystalsHPF: Few N=12,8,8,18,12	1			
Week12 CaC2O4CrystalsHPF: Moderate N=12,8,8,18,12	0			
Week12 CaC2O4CrystalsHPF: Many N=12,8,8,18,12	0			
Week12 CaC2O4CrystalsHPF: TNTC N=12,8,8,18,12	0			
Week16 CaC2O4CrystalsHPF: None seen N=13,6,5,12,14	14			
Week16 CaC2O4CrystalsHPF: Few N=13,6,5,12,14	0			
Week16 CaC2O4CrystalsHPF: Moderate N=13,6,5,12,14	0			
Week16 CaC2O4CrystalsHPF: Many N=13,6,5,12,14	0			
Week16 CaC2O4CrystalsHPF: TNTC N=13,6,5,12,14	0			
Baseline TPCrystalsHPF: None seen N=9,11,5,17,19	19			
Week2 TPCrystalsHPF: None seen N=8,9,3,11,18	18			
Week4 TPCrystalsHPF: None seen N=11,6,3,15,13	13			
Week12 TPCrystalsHPF: None seen N=12,8,8,18,12	12			
Week16 TPCrystalsHPF: None seen N=13,6,5,12,14	14			
Baseline UACrystalsHPF: None seen N=9,11,5,17,19	19			
Baseline UACrystalsHPF: Few N=9,11,5,17,19	0			
Baseline UACrystalsHPF: Moderate N=9,11,5,17,19	0			
Week2 UACrystalsHPF: None seen N=8,9,3,11,18	18			
Week2 UACrystalsHPF: Few N=8,9,3,11,18	0			
Week2 UACrystalsHPF: Moderate N=8,9,3,11,18	0			

Week4 UACrystalsHPF: None seen N=11,6,3,15,13	12			
Week4 UACrystalsHPF: Few N=11,6,3,15,13	1			
Week4 UACrystalsHPF: Moderate N=11,6,3,15,13	0			
Week12 UACrystalsHPF: None seen N=12,8,8,18,12	12			
Week12 UACrystalsHPF: Few N=12,8,8,18,12	0			
Week12 UACrystalsHPF: Moderate N=12,8,8,18,12	0			
Week16 UACrystalsHPF: None seen N=13,6,5,12,14	14			
Week16 UACrystalsHPF: Few N=13,6,5,12,14	0			
Week16 UACrystalsHPF: Moderate N=13,6,5,12,14	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On or after first dosing with randomised study treatment up to Week 16.

Adverse event reporting for the deaths (all causes) considers all deaths that occurred at any time during the study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo.

Reporting group title	40 mg Elinzanetant (BAY3427080)
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Reporting group description:

Subjects received 40 mg elinzanetant.

Reporting group title	160 mg Elinzanetant (BAY3427080)
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Reporting group description:

Subjects received 160 mg elinzanetant.

Reporting group title	120 mg Elinzanetant (BAY3427080)
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Reporting group description:

Subjects received 120 mg elinzanetant.

Reporting group title	80 mg Elinzanetant (BAY3427080)
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Reporting group description:

Subjects received 80 mg elinzanetant.

Serious adverse events	Placebo	40 mg Elinzanetant (BAY3427080)	160 mg Elinzanetant (BAY3427080)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 47 (4.26%)	0 / 31 (0.00%)	1 / 52 (1.92%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			

subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Sepsis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 47 (2.13%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	120 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 52 (1.92%)	1 / 17 (5.88%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 52 (1.92%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 52 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Sepsis			

subjects affected / exposed	0 / 52 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 52 (0.00%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	40 mg Elinzanetant (BAY3427080)	160 mg Elinzanetant (BAY3427080)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 47 (38.30%)	13 / 31 (41.94%)	23 / 52 (44.23%)
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 47 (0.00%)	3 / 31 (9.68%)	4 / 52 (7.69%)
occurrences (all)	0	3	4
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	1 / 47 (2.13%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 47 (0.00%)	2 / 31 (6.45%)	2 / 52 (3.85%)
occurrences (all)	0	2	2
Cough			

subjects affected / exposed occurrences (all)	2 / 47 (4.26%) 2	0 / 31 (0.00%) 0	0 / 52 (0.00%) 0
Psychiatric disorders			
Depressed mood			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 31 (0.00%)	1 / 52 (1.92%)
occurrences (all)	1	0	1
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 47 (2.13%)	1 / 31 (3.23%)	1 / 52 (1.92%)
occurrences (all)	1	1	1
Liver function test increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 47 (2.13%)	2 / 31 (6.45%)	1 / 52 (1.92%)
occurrences (all)	1	2	1
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Somnolence			
subjects affected / exposed	1 / 47 (2.13%)	3 / 31 (9.68%)	6 / 52 (11.54%)
occurrences (all)	2	3	6
Headache			

subjects affected / exposed occurrences (all)	6 / 47 (12.77%) 8	3 / 31 (9.68%) 3	4 / 52 (7.69%) 6
Dizziness subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 31 (0.00%) 0	3 / 52 (5.77%) 3
Gastrointestinal disorders Flatulence subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 31 (0.00%) 0	0 / 52 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	3 / 47 (6.38%) 3	2 / 31 (6.45%) 2	3 / 52 (5.77%) 3
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 31 (0.00%) 0	0 / 52 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 47 (4.26%) 2	2 / 31 (6.45%) 4	2 / 52 (3.85%) 2
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1	0 / 31 (0.00%) 0	1 / 52 (1.92%) 1
Renal and urinary disorders Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 31 (0.00%) 0	0 / 52 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 31 (0.00%) 0	0 / 52 (0.00%) 0
Musculoskeletal and connective tissue disorders Joint swelling subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1	0 / 31 (0.00%) 0	0 / 52 (0.00%) 0
Infections and infestations Viral upper respiratory tract infection			

subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Viral sinusitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 47 (2.13%)	2 / 31 (6.45%)	2 / 52 (3.85%)
occurrences (all)	1	2	2
Nasopharyngitis			
subjects affected / exposed	4 / 47 (8.51%)	1 / 31 (3.23%)	0 / 52 (0.00%)
occurrences (all)	4	1	0
Herpes zoster			
subjects affected / exposed	0 / 47 (0.00%)	0 / 31 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	120 mg Elinzanetant (BAY3427080)	80 mg Elinzanetant (BAY3427080)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 52 (44.23%)	14 / 17 (82.35%)	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 52 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	1 / 52 (1.92%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	1 / 52 (1.92%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 17 (0.00%)	
occurrences (all)	0	0	
Cough			

subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	1 / 17 (5.88%) 1	
Psychiatric disorders Depressed mood subjects affected / exposed occurrences (all)	2 / 52 (3.85%) 2	1 / 17 (5.88%) 1	
Insomnia subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	1 / 17 (5.88%) 1	
Investigations Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	1 / 17 (5.88%) 1	
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	3 / 52 (5.77%) 3	1 / 17 (5.88%) 2	
Liver function test increased subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	1 / 17 (5.88%) 1	
Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	1 / 17 (5.88%) 1	
Injury, poisoning and procedural complications Arthropod bite subjects affected / exposed occurrences (all)	1 / 52 (1.92%) 1	0 / 17 (0.00%) 0	
Cardiac disorders Bradycardia subjects affected / exposed occurrences (all)	0 / 52 (0.00%) 0	1 / 17 (5.88%) 1	
Nervous system disorders Somnolence subjects affected / exposed occurrences (all)	2 / 52 (3.85%) 2	1 / 17 (5.88%) 1	
Headache			

subjects affected / exposed	6 / 52 (11.54%)	2 / 17 (11.76%)	
occurrences (all)	7	2	
Dizziness			
subjects affected / exposed	3 / 52 (5.77%)	0 / 17 (0.00%)	
occurrences (all)	4	0	
Gastrointestinal disorders			
Flatulence			
subjects affected / exposed	0 / 52 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	3 / 52 (5.77%)	2 / 17 (11.76%)	
occurrences (all)	3	2	
Abdominal pain upper			
subjects affected / exposed	1 / 52 (1.92%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Nausea			
subjects affected / exposed	1 / 52 (1.92%)	2 / 17 (11.76%)	
occurrences (all)	1	2	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 52 (1.92%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 52 (1.92%)	1 / 17 (5.88%)	
occurrences (all)	1	2	
Haematuria			
subjects affected / exposed	0 / 52 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Joint swelling			
subjects affected / exposed	0 / 52 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Infections and infestations			
Viral upper respiratory tract infection			

subjects affected / exposed	2 / 52 (3.85%)	1 / 17 (5.88%)	
occurrences (all)	2	1	
Viral sinusitis			
subjects affected / exposed	0 / 52 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Urinary tract infection			
subjects affected / exposed	2 / 52 (3.85%)	0 / 17 (0.00%)	
occurrences (all)	2	0	
Nasopharyngitis			
subjects affected / exposed	3 / 52 (5.77%)	0 / 17 (0.00%)	
occurrences (all)	3	0	
Herpes zoster			
subjects affected / exposed	0 / 52 (0.00%)	2 / 17 (11.76%)	
occurrences (all)	0	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 February 2019	In addition to minor typographical and formatting corrections, the following changes were made: - Clinical Chemistry was added to Week 8 visit. - A footnote was added to Inclusion Criterion #3 to provide further clarity and guidance on the definition of post-menopausal status. - Haemoglobin A1c was added to the list of clinical chemistry parameters. - The CRO's name was updated from Pharm Olam International to Pharm Olam.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The secondary endpoint "change from baseline in clinical laboratory assessments" will be reported during the next update of the record.

Notes: