



Clinical trial results:

A Phase III, Randomized, Multicenter, Open-Label Study in Adolescent and Adult Participants Comparing the Efficacy and Safety of Gepotidacin to Ceftriaxone Plus Azithromycin in the Treatment of Uncomplicated Urogenital Gonorrhea Caused by Neisseria gonorrhoeae Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2018-001780-23 |
| Trial protocol | GB DE |
| Global end of trial date | 10 October 2023 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 17 May 2024 |
| First version publication date | 17 May 2024 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | BTZ116577 |
|-----------------------|-----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04010539 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS |
| Public contact | GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-002443-PIP02-18 |
| 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 | 14 February 2024 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 10 October 2023 |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 October 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

- 1) To evaluate the efficacy of oral gepotidacin compared to IM ceftriaxone plus oral azithromycin to treat participants with uncomplicated urogenital gonorrhea caused by *Neisseria gonorrhoeae* (NG)
- (2) To evaluate the efficacy of oral gepotidacin compared to IM ceftriaxone plus oral azithromycin to treat participants with rectal gonorrhea caused by NG
- (3) To evaluate the efficacy of oral gepotidacin compared to IM ceftriaxone plus oral azithromycin to treat participants with pharyngeal gonorrhea caused by NG
- (4) To evaluate the safety and tolerability of oral gepotidacin compared to IM ceftriaxone plus oral azithromycin

Protection of trial subjects:

Not Applicable

Background therapy:

Not Applicable

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 21 October 2019 |
| 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 | Australia: 105 |
| Country: Number of subjects enrolled | Germany: 139 |
| Country: Number of subjects enrolled | Mexico: 15 |
| Country: Number of subjects enrolled | United Kingdom: 98 |
| Country: Number of subjects enrolled | United States: 85 |
| Country: Number of subjects enrolled | Spain: 186 |
| Worldwide total number of subjects | 628 |
| EEA total number of subjects | 325 |

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) | 2 |
| Adults (18-64 years) | 623 |
| From 65 to 84 years | 3 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

None

Period 1

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

Arms

| | |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Gepotidacin |

Arm description:

Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive first dose of 3000 milligram (mg) (4*750 mg, tablets) gepotidacin orally on Day 1. Participants self-administered second dose of 3000 mg (4*750 mg, tablets) gepotidacin orally 10-12 hours after first dose. All doses were to be administered after food consumption and with water.

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

Dosage and administration details:

Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive first dose of 3000 milligram (mg) (4*750 mg, tablets) gepotidacin orally on Day 1. Participants self-administered second dose of 3000 mg (4*750 mg, tablets) gepotidacin orally 10-12 hours after first dose. All doses were to be administered after food consumption and with water.

| | |
|------------------|-------------------------------|
| Arm title | Ceftriaxone plus azithromycin |
|------------------|-------------------------------|

Arm description:

Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive single dose of 500 mg Ceftriaxone as intramuscular sterile powder reconstituted with appropriate diluent plus single oral dose of 1 gram (g) Azithromycin (2*500 mg, tablets) on Day 1. Azithromycin was to be administered after food consumption and with water.

| | |
|--|-------------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Ceftriaxone plus azithromycin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet, Powder for injection |
| Routes of administration | Oral use, Intramuscular use |

Dosage and administration details:

Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive single dose of 500 mg Ceftriaxone as intramuscular sterile powder reconstituted with appropriate diluent plus single oral dose of 1 gram (g) Azithromycin (2*500 mg, tablets) on Day 1. Azithromycin was to be administered after food consumption and with water.

| Number of subjects in period 1 | Gepotidacin | Ceftriaxone plus azithromycin |
|--|--------------------|-------------------------------|
| Started | 314 | 314 |
| Safety population | 309 | 313 |
| Microbiological ITT(Micro-ITT)population | 202 ^[1] | 204 ^[2] |
| Micro-ITT Rectal population | 26 ^[3] | 15 ^[4] |
| Micro-ITT Pharyngeal population | 18 ^[5] | 17 ^[6] |
| Completed | 294 | 295 |
| Not completed | 20 | 19 |
| Consent withdrawn by subject | 4 | 1 |
| Physician decision | - | 2 |
| Adverse event, non-fatal | 3 | - |
| Protocol Deviation | - | 1 |
| Randomized in Error/ Mistake | 2 | - |
| Participant Did Not Receive IP | - | 1 |
| Lost to follow-up | 10 | 14 |
| Eligibility Criteria Unable to Evaluate | 1 | - |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Intermediate milestones are a subset of started population. Hence number of participants at the milestones are less than started.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Intermediate milestones are a subset of started population. Hence number of participants at the milestones are less than started.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Intermediate milestones are a subset of started population. Hence number of participants at the milestones are less than started.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Intermediate milestones are a subset of started population. Hence number of participants at the milestones are less than started.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Intermediate milestones are a subset of started population. Hence number of participants at the milestones are less than started.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Intermediate milestones are a subset of started population. Hence number of participants at the milestones are less than started.

Baseline characteristics

Reporting groups

| | |
|---|-------------------------------|
| Reporting group title | Gepotidacin |
| Reporting group description: | |
| Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive first dose of 3000 milligram (mg) (4*750 mg, tablets) gepotidacin orally on Day 1. Participants self-administered second dose of 3000 mg (4*750 mg, tablets) gepotidacin orally 10-12 hours after first dose. All doses were to be administered after food consumption and with water. | |
| Reporting group title | Ceftriaxone plus azithromycin |
| Reporting group description: | |
| Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive single dose of 500 mg Ceftriaxone as intramuscular sterile powder reconstituted with appropriate diluent plus single oral dose of 1 gram (g) Azithromycin (2*500 mg, tablets) on Day 1. Azithromycin was to be administered after food consumption and with water. | |

| Reporting group values | Gepotidacin | Ceftriaxone plus azithromycin | Total |
|---|-------------|-------------------------------|-------|
| Number of subjects | 314 | 314 | 628 |
| Age categorical | | | |
| Units: Participants | | | |
| 12-84 years | 314 | 314 | 628 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 33.9 | 33.7 | |
| standard deviation | ± 10.42 | ± 10.70 | - |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 35 | 34 | 69 |
| Male | 279 | 280 | 559 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 9 | 10 | 19 |
| Asian | 12 | 17 | 29 |
| Native Hawaiian or Other Pacific Islander | 7 | 2 | 9 |
| Black or African American | 49 | 39 | 88 |
| White | 231 | 241 | 472 |
| More than one race | 6 | 5 | 11 |
| Unknown or Not Reported | 0 | 0 | 0 |

End points

End points reporting groups

| | |
|---|-------------------------------|
| Reporting group title | Gepotidacin |
| Reporting group description: Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive first dose of 3000 milligram (mg) (4*750 mg, tablets) gepotidacin orally on Day 1. Participants self-administered second dose of 3000 mg (4*750 mg, tablets) gepotidacin orally 10-12 hours after first dose. All doses were to be administered after food consumption and with water. | |
| Reporting group title | Ceftriaxone plus azithromycin |
| Reporting group description: Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive single dose of 500 mg Ceftriaxone as intramuscular sterile powder reconstituted with appropriate diluent plus single oral dose of 1 gram (g) Azithromycin (2*500 mg, tablets) on Day 1. Azithromycin was to be administered after food consumption and with water. | |

Primary: Number of Participants with Culture-Confirmed Bacterial Eradication of Neisseria Gonorrhoeae (NG) From the Urogenital Site at the Test-Of-Cure (TOC) Visit (Day 4 to 8) - Micro-ITT population

| | |
|---|--|
| End point title | Number of Participants with Culture-Confirmed Bacterial Eradication of Neisseria Gonorrhoeae (NG) From the Urogenital Site at the Test-Of-Cure (TOC) Visit (Day 4 to 8) - Micro-ITT population |
| End point description: Urogenital specimens obtained for bacteriological culture at Baseline and TOC visits were compared to determine microbiological outcome. Microbiological Success: Culture-confirmed elimination of baseline NG from a bacteriology sample taken at TOC visit without participant receiving other systemic antimicrobials before this visit. Microbiological Failure categorized as Bacterial Persistence (BP): Culture-confirmed persistence of baseline NG pathogen from a bacteriology sample taken at TOC visit without the participant receiving other systemic antimicrobials before this visit. Unable To Determine (UTD): Inability to determine TOC NG pathogen outcome (e.g no bacteriological sample taken for culture, sample lost, visit did not occur etc) or participant received other systemic antimicrobials before the TOC visit. | |
| End point type | Primary |
| End point timeframe: Baseline (Day 1) and TOC visit (Day 4 to 8) | |

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 202 | 204 | | |
| Units: Participants | | | | |
| Microbiological success | 187 | 186 | | |
| Microbiological failure, BP | 0 | 0 | | |
| Microbiological failure, UTD | 15 | 18 | | |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Statistical Analysis 2 |
| Statistical analysis description: | |
| The difference in microbiological success rates between treatment groups (Gepotidacin - Ceftriaxone plus azithromycin) was calculated using the Miettinen-Nurminen Summary Score Method adjusted for sex and sexual orientation combination. Superiority was declared if the lower limit of the 2-sided 95% confidence interval for the difference was above 0.0%. | |
| Comparison groups | Gepotidacin v Ceftriaxone plus azithromycin |
| Number of subjects included in analysis | 406 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5072 |
| Method | 1-sided p-value for TestOfSuperiority |
| Parameter estimate | Adjusted Difference in Percent |
| Point estimate | -0.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.6 |
| upper limit | 5.5 |

| | |
|--|---|
| Statistical analysis title | Statistical Analysis 1 |
| Statistical analysis description: | |
| The difference in microbiological success rates between treatment groups (Gepotidacin - Ceftriaxone plus azithromycin) was calculated using the Miettinen-Nurminen Summary Score Method adjusted for sex and sexual orientation combination. Non-inferiority was declared if the lower limit of the 2-sided 95% confidence interval for the difference was above -10.0%. | |
| Comparison groups | Gepotidacin v Ceftriaxone plus azithromycin |
| Number of subjects included in analysis | 406 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Adjusted Difference in Percent |
| Point estimate | -0.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.6 |
| upper limit | 5.5 |

Secondary: Number of Participants with Culture-Confirmed Bacterial Eradication of NG From the Rectal Site at the TOC visit - Micro-ITT rectal population

| | |
|-----------------|---|
| End point title | Number of Participants with Culture-Confirmed Bacterial Eradication of NG From the Rectal Site at the TOC visit - Micro-ITT rectal population |
|-----------------|---|

End point description:

Urogenital specimens obtained for bacteriological culture at Baseline and TOC visits were compared to determine microbiological outcome. Microbiological Success: Culture-confirmed elimination of baseline NG from a bacteriology sample taken at the TOC visit without participant receiving other systemic antimicrobials before this visit. Microbiological Failure categorized as BP: Culture-confirmed persistence of baseline NG pathogen from a bacteriology sample taken at the TOC visit without the participant receiving other systemic antimicrobials before this visit. UTD: Inability to determine the TOC NG

pathogen outcome (e.g., no bacteriological sample taken for culture, sample lost, visit did not occur etc.) or participant received other systemic antimicrobials before the TOC visit. Micro-ITT Rectal population: participants who met the definition of the Micro-ITT and have confirmed NG isolated that is ceftriaxone susceptible from baseline culture of their rectal specimen.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day 1) and TOC visit (Day 4 to 8) | |

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 26 | 15 | | |
| Units: Participants | | | | |
| Microbiological success | 26 | 12 | | |
| Microbiological failure, BP | 0 | 0 | | |
| Microbiological failure, UTD | 0 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Culture-Confirmed Bacterial Eradication of NG from the Pharyngeal Site at the TOC visit - Micro-ITT pharyngeal population

| | |
|-----------------|---|
| End point title | Number of Participants with Culture-Confirmed Bacterial Eradication of NG from the Pharyngeal Site at the TOC visit - Micro-ITT pharyngeal population |
|-----------------|---|

End point description:

Urogenital specimens obtained for bacteriological culture at Baseline and TOC visits were compared to determine microbiological outcome. Microbiological Success: Culture-confirmed elimination of baseline NG from a bacteriology sample taken at the TOC visit without participant receiving other systemic antimicrobials before this visit. Microbiological Failure categorized as BP: Culture-confirmed persistence of baseline NG pathogen from a bacteriology sample taken at the TOC visit without the participant receiving other systemic antimicrobials before this visit. UTD: Inability to determine the TOC NG pathogen outcome (e.g., no bacteriological sample taken for culture, sample lost, visit did not occur etc.) or participant received other systemic antimicrobials before the TOC visit. Micro-ITT Pharyngeal population: participants who met the definition of the Micro-ITT Population and have confirmed NG isolated that is ceftriaxone susceptible from baseline culture of their pharyngeal specimen

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day 1) and TOC visit (Day 4 to 8) | |

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 17 | | |
| Units: Participants | | | | |
| Microbiological success | 14 | 16 | | |
| Microbiological failure, BP | 2 | 0 | | |
| Microbiological failure, UTD | 2 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any treatment-emergent adverse events (TEAEs) and any serious adverse events (SAEs) - Safety population

| | |
|-----------------|---|
| End point title | Number of participants with any treatment-emergent adverse events (TEAEs) and any serious adverse events (SAEs) - Safety population |
|-----------------|---|

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. A TEAE is an event that emerges during treatment having been absent pretreatment or worsens relative to the pretreatment state. An SAE is defined as any untoward medical occurrence that, at any dose, results in death; was life threatening; required hospitalization or prolongation of existing hospitalization; resulted in disability/incapacity; was a congenital anomaly/birth defect.

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

End point timeframe:

Up to 21 days

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|-----------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 309 | 313 | | |
| Units: Participants | | | | |
| Any TEAEs | 230 | 104 | | |
| Any SAEs | 1 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (CFB) in Hematology Parameters: Basophils, Eosinophil, Leukocytes, Neutrophils, Platelets, Lymphocytes, Monocytes, Neutrophils and Nucleated Erythrocytes - Safety population

| | |
|-----------------|---|
| End point title | Change from Baseline (CFB) in Hematology Parameters: Basophils, Eosinophil, Leukocytes, Neutrophils, Platelets, |
|-----------------|---|

End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameters: basophils, eosinophil, leukocytes, neutrophils, platelets, lymphocytes, monocytes, neutrophils and nucleated erythrocytes. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

End point type Secondary

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|---|-------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 284 | 293 | | |
| Units: Giga cells per liter (10 ⁹ cells/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Basophils, Baseline (Day 1) | 0.044 (± 0.0196) | 0.045 (± 0.0222) | | |
| Basophils, CFB to TOC | 0.001 (± 0.0167) | 0.000 (± 0.0152) | | |
| Eosinophils, Baseline (Day 1) | 0.154 (± 0.2117) | 0.160 (± 0.1384) | | |
| Eosinophils, CFB to TOC | 0.009 (± 0.1289) | 0.018 (± 0.0827) | | |
| Leukocytes, Baseline (Day 1) | 7.143 (± 2.2808) | 7.507 (± 2.2045) | | |
| Leukocytes, CFB to TOC | -0.811 (± 1.8536) | -1.267 (± 1.9362) | | |
| Neutrophils, Baseline (Day 1) | 4.443 (± 1.9621) | 4.774 (± 1.9355) | | |
| Neutrophils, CFB to TOC | -1.062 (± 1.7309) | -1.473 (± 1.8860) | | |
| Platelets, Baseline (Day 1) | 260.3 (± 61.79) | 268.4 (± 69.26) | | |
| Platelets, CFB to TOC | 10.2 (± 32.14) | 9.7 (± 34.94) | | |
| Lymphocytes, Baseline (Day 1) | 1.934 (± 0.5941) | 1.948 (± 0.6321) | | |
| Lymphocytes, CFB to TOC | 0.277 (± 0.5205) | 0.245 (± 0.5511) | | |
| Monocytes, Baseline (Day 1) | 0.559 (± 0.2209) | 0.572 (± 0.1877) | | |
| Monocytes, CFB to TOC | -0.034 (± 0.1917) | -0.053 (± 0.1782) | | |
| Nucleated Erythrocytes, Baseline (Day 1) | 0.002 (± 0.0047) | 0.001 (± 0.0038) | | |
| Nucleated Erythrocytes, CFB to TOC | 0.000 (± 0.0070) | 0.001 (± 0.0059) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameters: Mean Corpuscular Hemoglobin Concentration (MCHC) and Hemoglobin (Hb) - Safety population

| | |
|-----------------|---|
| End point title | Change from Baseline in Hematology Parameters: Mean Corpuscular Hemoglobin Concentration (MCHC) and Hemoglobin (Hb) - Safety population |
|-----------------|---|

End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameters: mean corpuscular hemoglobin concentration and hemoglobin. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 284 | 293 | | |
| Units: Grams per liter (g/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| MCHC, Baseline (Day 1) | 318.5 (± 16.27) | 318.8 (± 16.12) | | |
| MCHC, CFB to TOC | 2.4 (± 10.67) | 0.3 (± 11.27) | | |
| Hb, Baseline (Day 1) | 149.1 (± 12.83) | 149.2 (± 12.58) | | |
| Hb, CFB to TOC | 0.00 (± 6.70) | 0.6 (± 6.92) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameter: Hematocrit - Safety population

| | |
|-----------------|--|
| End point title | Change from Baseline in Hematology Parameter: Hematocrit - Safety population |
|-----------------|--|

End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter: hematocrit. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|---------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 284 | 293 | | |
| Units: Percentage | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 0.4691 (± 0.04205) | 0.4687 (± 0.04104) | | |
| CFB to TOC | -0.0038 (± 0.02526) | 0.0012 (± 0.02666) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameter: Erythrocytes - Safety population

| | |
|-----------------|--|
| End point title | Change from Baseline in Hematology Parameter: Erythrocytes - Safety population |
|-----------------|--|

End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter: red blood cell (RBC) count. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--|------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 284 | 293 | | |
| Units: Trillion cells per liter (10 ¹² cells/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 4.911 (± 0.4722) | 4.926 (± 0.4601) | | |
| CFB to TOC | 0.003 (± 0.2261) | 0.019 (± 0.2332) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameter: Mean Corpuscular Hemoglobin (MCH) - Safety population

| | |
|-----------------|--|
| End point title | Change from Baseline in Hematology Parameter: Mean |
|-----------------|--|

End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter: mean corpuscular hemoglobin (MCH). Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

| |
|---|
| Baseline (Day 1) and TOC visit (Day 4 to 8) |
|---|

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|----------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 284 | 293 | | |
| Units: Picograms (pg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 30.46 (\pm 1.978) | 30.38 (\pm 1.987) | | |
| CFB to TOC | -0.03 (\pm 0.451) | 0.00 (\pm 0.594) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameter: Mean Corpuscular Volume (MCV) - Safety population

| | |
|-----------------|---|
| End point title | Change from Baseline in Hematology Parameter: Mean Corpuscular Volume (MCV) - Safety population |
|-----------------|---|

End point description:

Blood samples were collected for the assessment of change from baseline in hematology parameter: mean corpuscular volume (MCV). Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

| |
|---|
| Baseline (Day 1) and TOC visit (Day 4 to 8) |
|---|

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|----------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 284 | 293 | | |
| Units: Femtoliters (fL) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 95.79 (\pm 6.266) | 95.43 (\pm 6.760) | | |
| CFB to TOC | -0.85 (\pm 3.104) | -0.12 (\pm 3.084) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Chemistry Parameters: Urea Nitrogen (UN), Glucose, Calcium, Chloride, Sodium, Magnesium and Potassium - Safety population

| | |
|-----------------|--|
| End point title | Change from Baseline in Clinical Chemistry Parameters: Urea Nitrogen (UN), Glucose, Calcium, Chloride, Sodium, Magnesium and Potassium - Safety population |
|-----------------|--|

End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters: urea nitrogen (UN), glucose, calcium, chloride, sodium, magnesium and potassium. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|-------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 304 | 306 | | |
| Units: Millimoles per liter (mmol/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| UN, Baseline (Day 1) | 4.793 (± 1.4293) | 4.800 (± 1.4669) | | |
| UN, CFB to TOC | 0.190 (± 1.1640) | 0.282 (± 1.1920) | | |
| Glucose, Baseline | 5.049 (± 1.0557) | 5.090 (± 1.1183) | | |
| Glucose, CFB to TOC | 0.227 (± 0.9425) | 0.064 (± 0.9684) | | |
| Calcium, Baseline (Day 1) | 2.387 (± 0.0986) | 2.387 (± 0.0954) | | |
| Calcium, CFB to TOC | -0.009 (± 0.0852) | -0.015 (± 0.0871) | | |
| Chloride, Baseline (Day 1) | 101.7 (± 2.26) | 101.7 (± 2.30) | | |
| Chloride, CFB to TOC | 0.7 (± 2.57) | 0.5 (± 2.40) | | |
| Sodium, Baseline (Day 1) | 139.6 (± 2.11) | 139.6 (± 2.02) | | |
| Sodium, CFB to TOC | 0.2 (± 2.19) | 0.1 (± 2.44) | | |
| Magnesium, Baseline (Day 1) | 0.854 (± 0.0612) | 0.855 (± 0.0637) | | |
| Magnesium, CFB to TOC | -0.003 (± 0.0604) | -0.004 (± 0.0584) | | |
| Potassium, Baseline (Day 1) | 4.29 (± 0.323) | 4.30 (± 0.332) | | |

| | | | | |
|-----------------------|----------------------|----------------------|--|--|
| Potassium, CFB to TOC | -0.04 (\pm 0.336) | -0.03 (\pm 0.345) | | |
|-----------------------|----------------------|----------------------|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Chemistry Parameters: Bilirubin, Direct Bilirubin and Creatinine - Safety population

| | |
|--|---|
| End point title | Change from Baseline in Clinical Chemistry Parameters: Bilirubin, Direct Bilirubin and Creatinine - Safety population |
| End point description: Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters: bilirubin, direct bilirubin and creatinine levels. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. | |
| End point type | Secondary |
| End point timeframe: Baseline (Day 1) and TOC visit (Day 4 to 8) | |

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|----------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 303 | 305 | | |
| Units: Micromoles per liter (umol/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Bilirubin, Baseline (Day 1) | 8.54 (\pm 5.861) | 7.71 (\pm 4.806) | | |
| Bilirubin, CFB to TOC | -0.05 (\pm 5.025) | -0.14 (\pm 3.914) | | |
| Direct Bilirubin, Baseline (Day 1) | 3.83 (\pm 1.248) | 3.76 (\pm 1.210) | | |
| Direct Bilirubin, CFB to TOC | -0.02 (\pm 0.897) | 0.01 (\pm 0.876) | | |
| Creatinine, Baseline (Day 1) | 75.9 (\pm 34.12) | 75.0 (\pm 20.63) | | |
| Creatinine, CFB to TOC | -0.2 (\pm 34.08) | 2.6 (\pm 9.52) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Chemistry Parameters: Albumin and Protein - Safety population

| | |
|--|--|
| End point title | Change from Baseline in Clinical Chemistry Parameters: Albumin and Protein - Safety population |
| End point description: Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters: albumin and protein. Baseline (Day 1) was defined as the latest pre-dose assessment with | |

a non-missing value, including those from unscheduled visits.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day 1) and TOC visit (Day 4 to 8) | |

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 305 | 306 | | |
| Units: Grams per liter (g/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Albumin, Baseline (Day 1) | 46.9 (± 3.12) | 46.8 (± 3.19) | | |
| Albumin, CFB to TOC | -0.3 (± 2.35) | -0.3 (± 2.67) | | |
| Protein, Baseline (Day 1) | 73.1 (± 4.80) | 73.3 (± 4.85) | | |
| Protein, CFB to TOC | -0.5 (± 3.86) | -0.5 (± 4.02) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Chemistry Parameters: Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT) and Alkaline Phosphatase (ALP) - Safety population

| | |
|-----------------|--|
| End point title | Change from Baseline in Clinical Chemistry Parameters: Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT) and Alkaline Phosphatase (ALP) - Safety population |
|-----------------|--|

End point description:

Blood samples were collected for the assessment of change from baseline in clinical chemistry parameters: aspartate aminotransferase (AST), alanine aminotransferase (ALT) and alkaline phosphatase (ALP). Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day 1) and TOC visit (Day 4 to 8) | |

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|---|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 303 | 305 | | |
| Units: International units per Liter (IU/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| AST, Baseline (Day 1) | 24.4 (± 15.30) | 24.2 (± 16.29) | | |
| AST, CFB to TOC | 2.8 (± 19.51) | 0.9 (± 13.25) | | |
| ALT, Baseline (Day 1) | 23.7 (± 18.78) | 23.7 (± 14.35) | | |

| | | | | |
|-----------------------|----------------|----------------|--|--|
| ALT, CFB to TOC | 1.4 (± 12.59) | 1.1 (± 7.64) | | |
| ALP, Baseline (Day 1) | 76.0 (± 20.86) | 77.1 (± 26.53) | | |
| ALP, CFB to TOC | -0.4 (± 7.73) | -1.5 (± 7.80) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Urinalysis Dipstick Results - Safety population

| | |
|-----------------|---|
| End point title | Number of Participants with Urinalysis Dipstick Results - Safety population |
|-----------------|---|

End point description:

Urine samples were collected for urinalysis: Glucose, Protein, Occult Blood and Ketones. The dipstick test gives results in a semi-quantitative manner, and results can be read as Negative, Small, Moderate, Large, Positive, 5 milligram per deciliter (mg/dL), 20 mg/dL, 30 mg/dL 50 mg/dL, 100 mg/dL, 150 mg/dL and ≥ 500 mg/dL indicating concentrations in the urine sample. In the row title (Glucose, Baseline, Negative), Glucose indicates parameter, Baseline is the visit and Negative indicates the concentration in the urine sample. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|---|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 299 | 307 | | |
| Units: Participants | | | | |
| Glucose, Baseline (Day 1), Negative | 296 | 305 | | |
| Glucose, Baseline (Day 1), 150 mg/dL | 0 | 0 | | |
| Glucose, Baseline (Day 1), ≥ 500 mg/dL | 3 | 2 | | |
| Glucose, TOC, Negative | 284 | 283 | | |
| Glucose, TOC, 150 mg/dL | 1 | 1 | | |
| Glucose, TOC, ≥ 500 mg/dL | 2 | 1 | | |
| Ketones, Baseline (Day 1), Negative | 288 | 300 | | |
| Ketones, Baseline (Day 1), 5 mg/dL | 10 | 7 | | |
| Ketones, Baseline (Day 1), 20 mg/dL | 1 | 0 | | |
| Ketones, TOC, Negative | 279 | 279 | | |
| Ketones, TOC, 5 mg/dL | 7 | 6 | | |
| Ketones, TOC, 20 mg/dL | 1 | 0 | | |
| Occult Blood, Baseline (Day 1), Negative | 202 | 192 | | |
| Occult Blood, Baseline (Day 1), Small | 77 | 91 | | |
| Occult Blood, Baseline (Day 1), Moderate | 18 | 19 | | |
| Occult Blood, Baseline (Day 1), Large | 2 | 5 | | |
| Occult Blood, TOC, Negative | 251 | 252 | | |
| Occult Blood, TOC, Small | 30 | 24 | | |

| | | | | |
|--|-----|-----|--|--|
| Occult Blood, TOC, Moderate | 3 | 6 | | |
| Occult Blood, TOC, Large | 3 | 3 | | |
| Protein, Baseline (Day 1), Negative | 212 | 210 | | |
| Protein, Baseline (Day 1), 30 mg/dL | 79 | 83 | | |
| Protein, Baseline (Day 1), 100 mg/dL | 8 | 13 | | |
| Protein, Baseline (Day 1), >=500 mg/dL | 0 | 1 | | |
| Protein, TOC, Negative | 239 | 244 | | |
| Protein, TOC, 30 mg/dL | 46 | 37 | | |
| Protein, TOC, 100 mg/dL | 2 | 4 | | |
| Protein, TOC, >=500 mg/dL | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values in Specific Gravity of Urine - Safety population

| | |
|-----------------|--|
| End point title | Absolute Values in Specific Gravity of Urine - Safety population |
|-----------------|--|

End point description:

Urine samples were collected from participants to assess urine specific gravity. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|--------------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 299 | 307 | | |
| Units: Ratio | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 1.0211 (± 0.00750) | 1.0207 (± 0.00747) | | |
| TOC | 1.0211 (± 0.00720) | 1.0216 (± 0.00748) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values in Potential of Hydrogen (pH) of Urine - Safety population

| | |
|-----------------|--|
| End point title | Absolute Values in Potential of Hydrogen (pH) of Urine - Safety population |
|-----------------|--|

End point description:

Urine samples were collected from participants to assess urine pH. Baseline (Day 1) was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 299 | 307 | | |
| Units: pH | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 5.6 (± 0.69) | 5.6 (± 0.70) | | |
| TOC | 5.5 (± 0.64) | 5.4 (± 0.62) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Signs: Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) - Safety population

| | |
|-----------------|---|
| End point title | Change from Baseline in Vital Signs: Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) - Safety population |
|-----------------|---|

End point description:

SBP and DBP were measured in a semi-supine position after 5 minutes rest. Baseline (Day 1) is the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 307 | 313 | | |
| Units: Millimeters of mercury (mmHg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| SBP, Baseline (Day 1) | 123.9 (± 13.69) | 125.1 (± 14.41) | | |
| SBP, CFB to TOC | -0.4 (± 12.61) | -0.5 (± 12.86) | | |
| DBP, Baseline (Day 1) | 76.7 (± 10.77) | 77.2 (± 10.50) | | |
| DBP, CFB to TOC | 0.1 (± 9.10) | -0.9 (± 9.54) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Sign: Pulse Rate - Safety population

| | |
|-----------------|--|
| End point title | Change from Baseline in Vital Sign: Pulse Rate - Safety population |
|-----------------|--|

End point description:

Pulse rate was measured in a semi-supine position after 5 minutes rest. Baseline (Day 1) is the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 | 313 | | |
| Units: Beats per minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 73.0 (± 12.24) | 72.8 (± 12.20) | | |
| CFB to TOC | 2.2 (± 12.44) | 2.4 (± 12.33) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Sign: Temperature - Safety population

| | |
|-----------------|---|
| End point title | Change from Baseline in Vital Sign: Temperature - Safety population |
|-----------------|---|

End point description:

Temperature was measured after 5 minutes rest. Baseline (Day 1) is the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

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

End point timeframe:

Baseline (Day 1) and TOC visit (Day 4 to 8)

| End point values | Gepotidacin | Ceftriaxone plus azithromycin | | |
|--------------------------------------|-----------------|-------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 306 | 313 | | |
| Units: Celsius (C) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) | 36.45 (± 0.395) | 36.44 (± 0.457) | | |
| CFB to TOC | -0.03 (± 0.381) | -0.06 (± 0.485) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All cause mortality, non-serious adverse events (Non-SAEs) and serious adverse events (SAEs) were collected from Day 1 through the final follow-up visit (up to 21Days)

Adverse event reporting additional description:

Safety population included all participants who received at least 1 dose of study treatment.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 26.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------------------------|
| Reporting group title | Ceftriaxone plus azithromycin |
|-----------------------|-------------------------------|

Reporting group description:

Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive single dose of 500 mg Ceftriaxone as intramuscular sterile powder reconstituted with appropriate diluent plus single oral dose of 1 gram (g) Azithromycin (2*500 mg, tablets) on Day 1. Azithromycin was to be administered after food consumption and with water.

| | |
|-----------------------|-------------|
| Reporting group title | Gepotidacin |
|-----------------------|-------------|

Reporting group description:

Participants with uncomplicated urogenital gonorrhea (GC) were randomized to receive first dose of 3000 milligram (mg) (4*750 mg, tablets) gepotidacin orally on Day 1. Participants self-administered second dose of 3000 mg (4*750 mg, tablets) gepotidacin orally 10-12 hours after first dose. All doses were to be administered after food consumption and with water.

| Serious adverse events | Ceftriaxone plus azithromycin | Gepotidacin | |
|---|-------------------------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 313 (0.00%) | 1 / 309 (0.32%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 313 (0.00%) | 1 / 309 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events | Ceftriaxone plus azithromycin | Gepotidacin | |
|--|----------------------------------|--------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 81 / 313 (25.88%) | 230 / 309 (74.43%) | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 8 / 313 (2.56%) | 10 / 309 (3.24%) | |
| occurrences (all) | 8 | 10 | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 313 (0.64%) | 16 / 309 (5.18%) | |
| occurrences (all) | 2 | 19 | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 313 (0.00%) | 8 / 309 (2.59%) | |
| occurrences (all) | 0 | 9 | |
| Injection site pain | | | |
| subjects affected / exposed | 5 / 313 (1.60%) | 0 / 309 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Eye disorders | | | |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 313 (0.00%) | 6 / 309 (1.94%) | |
| occurrences (all) | 0 | 6 | |
| Gastrointestinal disorders | | | |
| Flatulence | | | |
| subjects affected / exposed | 1 / 313 (0.32%) | 20 / 309 (6.47%) | |
| occurrences (all) | 1 | 20 | |
| Vomiting | | | |
| subjects affected / exposed | 2 / 313 (0.64%) | 20 / 309 (6.47%) | |
| occurrences (all) | 2 | 21 | |
| Nausea | | | |
| subjects affected / exposed | 9 / 313 (2.88%) | 73 / 309 (23.62%) | |
| occurrences (all) | 9 | 80 | |
| Diarrhoea | | | |
| subjects affected / exposed | 30 / 313 (9.58%) | 151 / 309 (48.87%) | |
| occurrences (all) | 30 | 167 | |
| Abdominal distension | | | |

| | | | |
|---|------------------------|------------------------|--|
| subjects affected / exposed occurrences (all) | 2 / 313 (0.64%) 2 | 5 / 309 (1.62%) 5 | |
| Faeces soft subjects affected / exposed occurrences (all) | 1 / 313 (0.32%) 1 | 16 / 309 (5.18%) 16 | |
| Abdominal Pain subjects affected / exposed occurrences (all) | 3 / 313 (0.96%) 4 | 16 / 309 (5.18%) 17 | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 2 / 313 (0.64%) 2 | 4 / 309 (1.29%) 4 | |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 1 / 313 (0.32%) 1 | 6 / 309 (1.94%) 6 | |
| Skin and subcutaneous tissue disorders Hyperhidrosis subjects affected / exposed occurrences (all) | 0 / 313 (0.00%) 0 | 7 / 309 (2.27%) 8 | |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 4 / 313 (1.28%) 4 | 0 / 309 (0.00%) 0 | |
| Proctitis chlamydial subjects affected / exposed occurrences (all) | 1 / 313 (0.32%) 1 | 4 / 309 (1.29%) 4 | |
| Urethritis chlamydial subjects affected / exposed occurrences (all) | 0 / 313 (0.00%) 0 | 6 / 309 (1.94%) 6 | |
| Chlamydial infection subjects affected / exposed occurrences (all) | 10 / 313 (3.19%) 10 | 12 / 309 (3.88%) 12 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported