



Clinical trial results:

Phase IIb, randomized, double-blind, parallel-group study to assess the efficacy, safety, tolerability, and resistance profile of GSK3640254 in combination with dolutegravir compared to dolutegravir plus lamivudine in HIV-1 infected, treatment naïve adults

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2021-000016-28 |
| Trial protocol | FR DE PT ES IT |
| Global end of trial date | 11 May 2023 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 16 February 2024 |
| First version publication date | 16 February 2024 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 212483 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | ViiV Healthcare |
| Sponsor organisation address | 980 GreatWest Road, Brentford, Middlesex, United Kingdom, TW8 9GS |
| Public contact | ViiV Healthcare, GSK Response Center, 1 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.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 | 07 July 2023 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|-------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 11 May 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

To evaluate antiviral efficacy of GSK3640254 (all concentrations)+ DTG, relative to DTG+3TC at week 24 in HIV-1 infected ART (anti-retroviral therapy) naive participants.

Protection of trial subjects:

Not applicable.

Background therapy: -

Evidence for comparator: -

| | |
|---|----------------|
| Actual start date of recruitment | 18 August 2021 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Argentina: 8 |
| Country: Number of subjects enrolled | Canada: 2 |
| Country: Number of subjects enrolled | France: 1 |
| Country: Number of subjects enrolled | Germany: 7 |
| Country: Number of subjects enrolled | Italy: 4 |
| Country: Number of subjects enrolled | Portugal: 2 |
| Country: Number of subjects enrolled | Puerto Rico: 8 |
| Country: Number of subjects enrolled | South Africa: 7 |
| Country: Number of subjects enrolled | Spain: 36 |
| Country: Number of subjects enrolled | United States: 10 |
| Worldwide total number of subjects | 85 |
| EEA total number of subjects | 50 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 | 0 |

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

Subject disposition

Recruitment

Recruitment details:

This study assessed efficacy, safety and resistance of GSK3640254 in combination with dolutegravir (DTG) compared to DTG+lamivudine in HIV-1 infected treatment-naïve adults. Study was terminated after primary analysis as the sponsor determined further development of study regimen would not be differentiated enough from existing similar regimens.

Pre-assignment

Screening details:

The changes from the planned subsequent analyses were presented as pre-specified in Statistical Analysis Plan. Secondary analyses at week 48 were not evaluated. Safety analysis is presented based on the Entire Duration of Treatment Exposure period, defined as from Day 1 up to end of continued access to treatment post-study termination (Day 478).

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, Assessor |

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg |

Arm description:

Participants with human immunodeficiency virus type 1 (HIV-1) orally received low dose (100 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24.

| | |
|--|----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Dolutegravir (50 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

One 50 mg tablet administered daily via oral administration

| | |
|--|---------------------|
| Investigational medicinal product name | GSK3640254 (100 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

One or more tablets (equivalent of 100 mg product) administered daily via oral administration

| | |
|------------------|-------------------------------|
| Arm title | GSK3640254 150 mg + DTG 50 mg |
|------------------|-------------------------------|

Arm description:

Participants with HIV-1 orally received medium dose (150 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|-------------------------------------|
| Investigational medicinal product name | Dolutegravir (50 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| One 50 mg tablet administered daily via oral administration | |
| Investigational medicinal product name | GSK3640254 (150 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| One or more tablets (equivalent of 150 mg product) administered daily via oral administration | |
| Arm title | GSK3640254 200 mg + DTG 50 mg |
| Arm description: | |
| Participants with HIV-1 orally received high dose (200 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24. | |
| Arm type | Experimental |
| Investigational medicinal product name | Dolutegravir (50 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| One 50 mg tablet administered daily via oral administration | |
| Investigational medicinal product name | GSK3640254 (200 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| One or more tablets (equivalent of 200 mg product) administered daily via oral administration | |
| Arm title | DTG 50 mg + Lamivudine (3TC) 300 mg |
| Arm description: | |
| Participants with HIV-1 orally received unblinded 50 mg DTG one tablet and blinded 300 mg 3TC. Each participant received one capsule per day of each intervention up to Week 24. | |
| Arm type | Active comparator |
| Investigational medicinal product name | Lamivudine (300 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| One 300 mg capsule administered daily via oral administration | |
| Investigational medicinal product name | Dolutegravir (50 mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| One 50 mg tablet administered daily via oral administration | |

| Number of subjects in period 1 | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg |
|--|--|-------------------------------|-------------------------------|
| Started | 22 | 20 | 22 |
| Completed | 2 | 3 | 2 |
| Not completed | 20 | 17 | 20 |
| Consent withdrawn by subject | - | 1 | - |
| Protocol-defined stopping criteria reached | - | - | 2 |
| Adverse event, non-fatal | 1 | - | 1 |
| Protocol Deviation | 1 | 1 | - |
| Study terminated by sponsor | 18 | 15 | 17 |
| Lost to follow-up | - | - | - |

| Number of subjects in period 1 | DTG 50 mg + Lamivudine (3TC) 300 mg |
|--|-------------------------------------|
| Started | 21 |
| Completed | 3 |
| Not completed | 18 |
| Consent withdrawn by subject | - |
| Protocol-defined stopping criteria reached | 2 |
| Adverse event, non-fatal | 1 |
| Protocol Deviation | - |
| Study terminated by sponsor | 14 |
| Lost to follow-up | 1 |

Baseline characteristics

Reporting groups

| | |
|---|--|
| Reporting group title | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg |
| Reporting group description: Participants with human immunodeficiency virus type 1 (HIV-1) orally received low dose (100 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24. | |
| Reporting group title | GSK3640254 150 mg + DTG 50 mg |
| Reporting group description: Participants with HIV-1 orally received medium dose (150 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24. | |
| Reporting group title | GSK3640254 200 mg + DTG 50 mg |
| Reporting group description: Participants with HIV-1 orally received high dose (200 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24. | |
| Reporting group title | DTG 50 mg + Lamivudine (3TC) 300 mg |
| Reporting group description: Participants with HIV-1 orally received unblinded 50 mg DTG one tablet and blinded 300 mg 3TC. Each participant received one capsule per day of each intervention up to Week 24. | |

| Reporting group values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg |
|---|--|-------------------------------|-------------------------------|
| Number of subjects | 22 | 20 | 22 |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 22 | 20 | 22 |
| Age Continuous Units: Years | | | |
| arithmetic mean | 34.2 | 36.9 | 32.6 |
| standard deviation | ± 7.53 | ± 10.51 | ± 8.41 |
| Sex: Female, Male Units: Participants | | | |
| Female | 3 | 4 | 5 |
| Male | 19 | 16 | 17 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| Asian | 0 | 0 | 0 |
| Black or African American | 3 | 4 | 3 |
| White | 18 | 14 | 16 |
| Mixed Race | 0 | 1 | 1 |
| Other - Unspecified | 1 | 1 | 2 |

| Reporting group values | DTG 50 mg + Lamivudine (3TC) 300 mg | Total | |
|------------------------------------|-------------------------------------|-------|--|
| Number of subjects | 21 | 85 | |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 21 | 85 | |

| | | | |
|---|----------------|----|--|
| Age Continuous Units: Years arithmetic mean standard deviation | 32.1 ± 8.62 | - | |
| Sex: Female, Male Units: Participants | | | |
| Female | 3 | 15 | |
| Male | 18 | 70 | |
| Race/Ethnicity, Customized Units: Subjects | | | |
| Asian | 1 | 1 | |
| Black or African American | 3 | 13 | |
| White | 14 | 62 | |
| Mixed Race | 0 | 2 | |
| Other - Unspecified | 3 | 7 | |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg |
| Reporting group description: Participants with human immunodeficiency virus type 1 (HIV-1) orally received low dose (100 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24. | |
| Reporting group title | GSK3640254 150 mg + DTG 50 mg |
| Reporting group description: Participants with HIV-1 orally received medium dose (150 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24. | |
| Reporting group title | GSK3640254 200 mg + DTG 50 mg |
| Reporting group description: Participants with HIV-1 orally received high dose (200 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24. | |
| Reporting group title | DTG 50 mg + Lamivudine (3TC) 300 mg |
| Reporting group description: Participants with HIV-1 orally received unblinded 50 mg DTG one tablet and blinded 300 mg 3TC. Each participant received one capsule per day of each intervention up to Week 24. | |

Primary: Percentage of participants with plasma HIV-1 ribonucleic acid (RNA) less than (<)50 copies per milliliter (c/mL) at Week 24

| | |
|---|--|
| End point title | Percentage of participants with plasma HIV-1 ribonucleic acid (RNA) less than (<)50 copies per milliliter (c/mL) at Week 24 ^[1] |
| End point description: Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 24 using the Food and Drug Administration (FDA) snapshot algorithm was assessed to evaluate the antiviral activity in HIV-1 infected ART (anti-retroviral therapy)-naïve participants. Analysis was performed on Intent-to-Treat Exposed (ITT-E) Population included all randomized participants who received at least one dose of study intervention and had data for plasma HIV-1 RNA <50 c/mL as per timeline assessed. | |
| End point type | Primary |
| End point timeframe: At Week 24 | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was descriptive, hence no statistical analysis was performed.

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|-----------------------------------|--|-------------------------------|-------------------------------|-------------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: Percentage of participants | 95 | 85 | 77 | 86 |

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values of HIV-1 RNA through Week 24

| | |
|---|--|
| End point title | Absolute values of HIV-1 RNA through Week 24 |
| End point description: Plasma samples were collected for quantitative analysis of HIV-1 RNA. Logarithm to base 10 (log 10) values for plasma HIV-1 RNA has been presented. Baseline is defined as the latest non-missing value prior to first dose of treatment according to date and time including unscheduled visits. Analysis was performed on ITT-E Population that had data for absolute values of HIV-1 RNA as per timeline assessed. | |
| End point type | Secondary |
| End point timeframe: At Baseline (Day 1) and Week 24 | |

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|--|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: log10 copies per milliliter(log10 c/mL) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) (N=22,20,22,21) | 4.614 (± 0.5253) | 4.446 (± 0.5913) | 4.535 (± 0.4165) | 4.179 (± 0.5907) |
| Week 24 (N=21,19,20,19) | 1.315 (± 0.0737) | 1.532 (± 0.7086) | 1.349 (± 0.1431) | 1.379 (± 0.2439) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HIV-1 RNA through Week 24

| | |
|--|---|
| End point title | Change from Baseline in HIV-1 RNA through Week 24 |
| End point description: Plasma samples were collected for quantitative analysis of HIV-1 RNA. Logarithm to base 10 (log 10) values for plasma HIV-1 RNA has been presented. Change from Baseline is defined as post-dose visit value minus Baseline value. Analysis was performed on ITT-E Population that had data for absolute values of HIV-1 RNA as per timeline assessed. | |
| End point type | Secondary |
| End point timeframe: At Week 24 compared to baseline (Day 1) | |

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|--------------------------------------|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 20 | 19 |
| Units: log ₁₀ c/mL | | | | |
| arithmetic mean (standard deviation) | -3.306 (± 0.5163) | -2.874 (± 0.8476) | -3.186 (± 0.4809) | -2.767 (± 0.5531) |

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values of cluster of differentiation 4+ (CD4+) T-cell counts through Week 24

| | |
|---|---|
| End point title | Absolute values of cluster of differentiation 4+ (CD4+) T-cell counts through Week 24 |
| End point description: | |
| Blood samples were collected and CD4+ cell count assessment by flow cytometry was carried out to evaluate the immunologic activity. Baseline is defined as the latest non-missing value prior to first dose of treatment according to date and time including unscheduled visits. | |
| Analysis was performed on ITT-E Population that had data for CD4+ T-cells analysis as per timeline assessed. | |
| End point type | Secondary |
| End point timeframe: | |
| At Baseline (Day 1) and Week 24 | |

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|---|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: cells per cubic millimeter (cells/mm ³) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1) (N=22,20,22,21) | 436.7 (± 161.93) | 451.4 (± 164.86) | 534.8 (± 200.99) | 506.9 (± 165.14) |
| Week 24 (N=22,20,19,21) | 753.4 (± 222.73) | 661.0 (± 193.50) | 756.1 (± 267.69) | 627.5 (± 175.94) |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CD4+ T-cell counts through Week 24

| | |
|-----------------|--|
| End point title | Change from Baseline in CD4+ T-cell counts through Week 24 |
|-----------------|--|

End point description:

Blood samples were collected and CD4+ cell count assessment was carried out to evaluate the immunologic activity. Change from Baseline is defined as post-dose visit value minus Baseline value. Analysis was performed on ITT-E Population that had data for CD4+ T-cells analysis as per timeline assessed.

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

End point timeframe:

At Week 24 compared to baseline (Day 1)

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|--------------------------------------|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 19 | 19 | 19 |
| Units: cells/mm ³ | | | | |
| arithmetic mean (standard deviation) | 317.7 (± 175.42) | 200.6 (± 126.68) | 241.2 (± 168.83) | 139.5 (± 126.63) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with serious adverse events (SAEs) and deaths, up to end of continued access to treatment post-study termination (Day 478)

| | |
|-----------------|---|
| End point title | Number of participants with serious adverse events (SAEs) and deaths, up to end of continued access to treatment post-study termination (Day 478) |
|-----------------|---|

End point description:

An SAE is defined as any serious adverse event that, at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity and is a congenital anomaly/birth defect.

The study was terminated by the sponsor after primary analysis (at week 24). Adverse event data were collected up to end of continued access to treatment post-study termination (Day 478).

Analysis performed on Safety population, that included all randomized participants who took at least 1 dose of study intervention.

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

End point timeframe:

From Day 1 up to end of continued access to treatment post-study termination (Day 478)

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|-----------------------------|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: Participants | | | | |
| SAEs | 2 | 0 | 0 | 1 |
| Death | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events (AEs) leading to discontinuation, up to end of continued access to treatment post-study termination (Day 478)

| | |
|-----------------|--|
| End point title | Number of participants with adverse events (AEs) leading to discontinuation, up to end of continued access to treatment post-study termination (Day 478) |
|-----------------|--|

End point description:

Number of participants who discontinued treatment due to AEs are presented.

The study was terminated by the sponsor after primary analysis (at week 24). Adverse event data were collected up to end of continued access to treatment post-study termination (Day 478).

Analysis performed on Safety population, that included all randomized participants who took at least 1 dose of study intervention.

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

End point timeframe:

From Day 1 up to end of continued access to treatment post-study termination (Day 478)

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|-----------------------------|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: Participants | 1 | 0 | 1 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events of special interest (AESIs), up to end of continued access to treatment post-study termination (Day 478)

| | |
|-----------------|---|
| End point title | Number of participants with adverse events of special interest (AESIs), up to end of continued access to treatment post-study termination (Day 478) |
|-----------------|---|

End point description:

AEs of special interest (AESIs) included AEs related to QT prolongation, gastrointestinal (GI) intolerability/toxicity, psychiatric events, nervous system disorders, skin and subcutaneous tissue disorders and cardiac disorders.

The study was terminated by the sponsor after primary analysis (at week 24). Adverse event data were collected up to end of continued access to treatment post-study termination (Day 478).

Analysis performed on Safety population, that included all randomized participants who took at least 1 dose of study intervention.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Day 1 up to end of continued access to treatment post-study termination (Day 478) | |

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|--|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: Participants | | | | |
| AEs related to QT prolongation | 0 | 0 | 0 | 0 |
| AEs related to GI intolerance/toxicity | 5 | 7 | 8 | 5 |
| AEs related to psychiatric events | 0 | 3 | 0 | 4 |
| AEs related to nervous system disorders | 2 | 4 | 5 | 2 |
| AEs related to skin, subcutaneous tissue disorder | 4 | 0 | 4 | 0 |
| AEs related to cardiac disorders | 1 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who develop phenotypic resistance up to Week 24

| | |
|-----------------|--|
| End point title | Number of participants who develop phenotypic resistance up to Week 24 |
|-----------------|--|

End point description:

Blood samples were collected for drug resistance testing to assess the development of viral resistance to GSK3640254 and other on-study Anti-Retroviral Therapy (ART) in participants experiencing virologic failure through Week 24. Only plasma HIV-1 RNA values determined by the central laboratory were used to assess virologic failure. PDVF was defined as having virologic non-response (HIV-1 RNA <1.0 log₁₀ c/mL reduction from baseline and <200 copies/mL by Week 12, confirmed levels ≥200 c/mL at or after Week 24 and plasma HIV-1 RNA ≤50 c/mL from testing on Week 24, virologic rebound (confirmed HIV-1 RNA ≥200 copies/mL after confirmed consecutive HIV-1 RNA <50 copies/mL). Analysis was performed on ITT-E population.

| | |
|--------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Day 1 up to Week 24 | |

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|-----------------------------|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: Participants | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who develop genotypic resistance up to Week 24

| | |
|-----------------|---|
| End point title | Number of participants who develop genotypic resistance up to Week 24 |
|-----------------|---|

End point description:

Blood samples were collected for drug resistance testing to assess the development of viral resistance to GSK3640254 through Week 24. New mutations were tabulated by drug class: integrase strand transfer inhibitor (INSTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), nucleoside reverse transcriptase inhibitor (NRTI) and protease inhibitor (PI).

Protocol-Defined Virologic Failure (PDVF) was defined as having virologic non-response (HIV-1 RNA <1.0 log₁₀ c/mL reduction from baseline and <200 copies/mL by Week 12, confirmed levels ≥ 200 c/mL at or after Week 24 and plasma HIV-1 RNA ≤ 50 c/mL from testing on Week 24, virologic rebound (confirmed HIV-1 RNA ≥ 200 copies/mL after confirmed consecutive HIV-1 RNA <50 copies/mL). Analysis was performed on ITT-E population.

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

End point timeframe:

From Day 1 up to Week 24

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | DTG 50 mg + Lamivudine (3TC) 300 mg |
|-----------------------------|---|-------------------------------------|-------------------------------------|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 20 | 22 | 21 |
| Units: Participants | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Trough concentration (C_{trough}) of GSK3640254 at Weeks 2, 4, 8, 12 and 24

| | |
|-----------------|--|
| End point title | Trough concentration (C _{trough}) of GSK3640254 at Weeks 2, 4, 8, 12 and 24 ^[2] |
|-----------------|--|

End point description:

Trough concentration (C_{trough}) is the concentration reached by a drug immediately before the next dose is administered. This was determined to assess the steady-state exposure of GSK3640254 when given in combination with DTG.

Analysis performed on Pharmacokinetic population, which included all participants who received GSK3640254, underwent sparse PK sampling during the study, and provided evaluable GSK3640254 plasma concentration data, demographic and baseline characteristics, and/or information on concomitant medications. Only those participants with data available at specified time points were

analyzed for the specific category titles.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Weeks 2, 4, 8, 12 (PRE DOSE), 12 (2-6HR POST DOSE), 24 (PRE DOSE), 24 (2-6HR POST DOSE) | |

Notes:

[2] - 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 presented the Ctrough analysis only for the arms that received one of the GSK3640254 doses (administered along with DTG), hence the DTG 50 mg + Lamivudine (3TC) 300 mg arm was not included in this endpoint.

| End point values | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg | |
|---|---|-------------------------------------|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 22 | 20 | 22 | |
| Units: nanogram per milliliter (ng/mL) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Week 2 (N=21,19,22) | 340.2 (269.5 to 411.0) | 549.9 (390.9 to 708.9) | 724.2 (563.4 to 885.0) | |
| Week 4 (N=21,20,21) | 417.8 (330.5 to 505.0) | 632.7 (470.4 to 795.0) | 799.6 (640.9 to 958.3) | |
| Week 8 (N=22,20,22) | 386.2 (293.7 to 478.6) | 646.6 (421.7 to 871.5) | 821.1 (620.2 to 1022.0) | |
| Week 12 (PRE DOSE) (N=22,20,22) | 481.3 (388.6 to 574.0) | 611.4 (430.6 to 792.1) | 877.2 (704.1 to 1050.3) | |
| Week 12 (2-6HR POST DOSE) (N=21,20,21) | 767.8 (612.3 to 923.3) | 1081.2 (759.5 to 1402.8) | 1658.1 (1305.8 to 2010.4) | |
| Week 24 (PRE DOSE) (N=21,19,19) | 396.0 (331.0 to 460.8) | 570.1 (333.6 to 806.6) | 848.8 (600.3 to 1097.4) | |
| Week 24 (2-6HR POST DOSE) (N=20,20,19) | 759.0 (623.1 to 894.8) | 1107.0 (660.8 to 1553.2) | 1584.1 (1067.3 to 2100.9) | |

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 up to end of continued access to treatment post-study termination (Day 478).

Adverse event reporting additional description:

The study was terminated by the sponsor after primary analysis (at week 24). As prespecified in Statistical analysis plan, AEs were collected up to end of continued access to treatment post-study termination (Day 478).

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

Dictionary used

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

| | |
|--------------------|-------|
| Dictionary version | v26.0 |
|--------------------|-------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg |
|-----------------------|--|

Reporting group description:

Participants with human immunodeficiency virus type 1 (HIV-1) orally received low dose (100 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24.

| | |
|-----------------------|-------------------------------|
| Reporting group title | GSK3640254 150 mg + DTG 50 mg |
|-----------------------|-------------------------------|

Reporting group description:

Participants with HIV-1 orally received medium dose (150 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24.

| | |
|-----------------------|-------------------------------|
| Reporting group title | GSK3640254 200 mg + DTG 50 mg |
|-----------------------|-------------------------------|

Reporting group description:

Participants with HIV-1 orally received high dose (200 mg) GSK3640254 tablet blinded and 50 mg DTG unblinded. Each participant received one tablet per day of each intervention up to Week 24.

| | |
|-----------------------|-------------------------------------|
| Reporting group title | DTG 50 mg + Lamivudine (3TC) 300 mg |
|-----------------------|-------------------------------------|

Reporting group description:

Participants with HIV-1 orally received unblinded 50 mg DTG one tablet and blinded 300 mg 3TC. Each participant received one capsule per day of each intervention up to Week 24.

| Serious adverse events | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg |
|--|--|-------------------------------|-------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 20 (0.00%) | 0 / 22 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Guillain-Barre syndrome | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 0 / 22 (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 |
| General disorders and administration site conditions | | | |

| | | | |
|--|---|----------------|----------------|
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 0 / 22 (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 |
| Gastrointestinal disorders | | | |
| Anogenital dysplasia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 20 (0.00%) | 0 / 22 (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 |
| | | | |
| Serious adverse events | DTG 50 mg + Lamivudine (3TC) 300 mg | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Nervous system disorders | | | |
| Guillain-Barre syndrome | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Anogenital dysplasia | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 2 %

| Non-serious adverse events | GSK3640254 100 mg + Dolutegravir (DTG) 50 mg | GSK3640254 150 mg + DTG 50 mg | GSK3640254 200 mg + DTG 50 mg |
|---|---|--------------------------------------|--------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 16 / 22 (72.73%) | 15 / 20 (75.00%) | 17 / 22 (77.27%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 20 (5.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Investigations | | | |
| Blood pressure increased | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 20 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 20 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 2 |
| Nervous system disorders | | | |
| Somnolence | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Headache | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 3 / 20 (15.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 2 | 4 | 3 |
| Sciatica | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 20 (5.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 20 (10.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| General disorders and administration site conditions | | | |
| Influenza like illness | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 2 / 20 (10.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 2 | 2 | 1 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Pyrexia | | | |

| | | | |
|--|---------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 3 / 20 (15.00%) 3 | 0 / 22 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 20 (10.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 20 (5.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 1 | 1 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Faeces soft | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 4 / 20 (20.00%) | 5 / 22 (22.73%) |
| occurrences (all) | 2 | 6 | 6 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 20 (10.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 20 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 0 | 0 | 2 |
| Reproductive system and breast disorders | | | |

| | | | |
|--|---------------------|----------------------|----------------------|
| Vascular disorders Hypertension subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 20 (0.00%) 0 | 1 / 22 (4.55%) 1 |
| Erectile dysfunction subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 20 (0.00%) 0 | 1 / 22 (4.55%) 1 |
| Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 20 (5.00%) 1 | 1 / 22 (4.55%) 1 |
| Cough subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 2 / 20 (10.00%) 2 | 0 / 22 (0.00%) 0 |
| Catarrh subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 20 (0.00%) 0 | 1 / 22 (4.55%) 1 |
| Skin and subcutaneous tissue disorders Skin lesion subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 22 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 0 / 20 (0.00%) 0 | 3 / 22 (13.64%) 3 |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 2 / 20 (10.00%) 2 | 0 / 22 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Rotator cuff syndrome subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 1 / 20 (5.00%) 1 | 0 / 22 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 2 / 20 (10.00%) 2 | 0 / 22 (0.00%) 0 |
| Arthralgia | | | |

| | | | |
|--|---------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 2 / 20 (10.00%) 2 | 1 / 22 (4.55%) 1 |
| Infections and infestations | | | |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 20 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Urethritis chlamydial | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 2 / 20 (10.00%) | 5 / 22 (22.73%) |
| occurrences (all) | 3 | 2 | 5 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| Influenza | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 20 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Monkeypox | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 20 (5.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 1 | 1 | 5 |
| Oropharyngeal gonococcal infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Pharyngeal chlamydia infection | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 20 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 20 (5.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 1 | 2 | 2 |

| | | | |
|-----------------------------------|----------------|----------------|----------------|
| Pharyngotonsillitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 20 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 20 (5.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 20 (5.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 1 / 20 (5.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 2 | 1 | 2 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 2 | 1 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 20 (5.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 20 (5.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 0 | 1 | 2 |

| | | | |
|---|---|--|--|
| Non-serious adverse events | DTG 50 mg + Lamivudine (3TC) 300 mg | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 14 / 21 (66.67%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Investigations | | | |
| Blood pressure increased | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|--|---------------------|--|--|
| Ligament sprain subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Nervous system disorders | | | |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Headache subjects affected / exposed occurrences (all) | 2 / 21 (9.52%) 5 | | |
| Sciatica subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Dizziness subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| General disorders and administration site conditions | | | |
| Influenza like illness subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Gastrointestinal disorders | | | |
| Vomiting subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Toothache subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Nausea subjects affected / exposed occurrences (all) | 2 / 21 (9.52%) 2 | | |

| | | | |
|---|----------------|--|--|
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences (all) | 1 | | |
| Faeces soft | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences (all) | 2 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 21 (9.52%) | | |
| occurrences (all) | 2 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reproductive system and breast disorders | | | |
| Vascular disorders Hypertension | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences (all) | 1 | | |
| Erectile dysfunction | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cough | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Catarrh | | | |

| | | | |
|--|----------------------|--|--|
| subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Skin and subcutaneous tissue disorders Skin lesion subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Rash subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Musculoskeletal and connective tissue disorders Rotator cuff syndrome subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Back pain subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Arthralgia subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |
| Infections and infestations Folliculitis subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| Urethritis chlamydial subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | | |
| COVID-19 subjects affected / exposed occurrences (all) | 3 / 21 (14.29%) 3 | | |
| Herpes simplex subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | | |

| | | | |
|------------------------------------|-----------------|--|--|
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Influenza | | | |
| subjects affected / exposed | 3 / 21 (14.29%) | | |
| occurrences (all) | 3 | | |
| Monkeypox | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences (all) | 1 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 3 / 21 (14.29%) | | |
| occurrences (all) | 3 | | |
| Oropharyngeal gonococcal infection | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences (all) | 1 | | |
| Pharyngeal chlamydia infection | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngotonsillitis | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences (all) | 1 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 3 / 21 (14.29%) | | |
| occurrences (all) | 6 | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | | |
| occurrences (all) | 1 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Viral infection | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroeneteritis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | | |
| occurrences (all) | 0 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 02 September 2022 | The changes in this amendments were the reduction of the sample size of the participants and adjustment of number of participants among the 3 experimental arms. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported