

**Clinical trial results:****A Multicenter, Adaptive, Randomised Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults - Version for European Union/United Kingdom Sites****Summary**

| | |
|--------------------------|-------------------|
| EudraCT number | 2020-001052-18 |
| Trial protocol | DK GB DE GR ES |
| Global end of trial date | 10 September 2020 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 01 April 2021 |
| First version publication date | 01 April 2021 |
| Summary attachment (see zip file) | ACTT-1 final results (ACTT-1_final_results-paper_nejm_08Oct2020.pdf) ACTT-2 final results (ACTT-2_Publication_NEJM_11Dec2020.pdf) |

Trial information**Trial identification**

| | |
|-----------------------|-----|
| Sponsor protocol code | 010 |
|-----------------------|-----|

Additional study identifiers

| | |
|------------------------------------|--------------------------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04280705 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | DMID - NIH: 20-0006, Version no. 6.0 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | US NIAID, Div. of Microbiology and Infectious Diseases (DMID) National Institute of Health (NIH) |
| Sponsor organisation address | 5601 Fishers Lane, Bethesda, United States, MD 20892-9806 |
| Public contact | Janice Arega, US NIAID, Div. of Microbiology and Infectious Diseases (DMID) National Institute of Health (NIH), +1 240292-0928, aregaj@niaid.nih.gov |
| Scientific contact | Janice Arega, US NIAID, Div. of Microbiology and Infectious Diseases (DMID) National Institute of Health (NIH), +1 240292-0928, aregaj@niaid.nih.gov |
| Sponsor organisation name | University of Minnesota |
| Sponsor organisation address | 420 Johnston Hall, 101 Pleasant St. SE, Minneapolis, United States, 55455 |
| Public contact | Eileen Denning, Coordinating Centers for Biometric Research, Div. of Biostatistics, School of Public Health, edenning@umn.edu |
| Scientific contact | James D. Neaton, Coordinating Centers for Biometric Research, Div. of Biostatistics, School of Public Health, neato001@umn.edu |

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 | 09 December 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 21 May 2020 |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 September 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the clinical efficacy, as assessed by time to recovery, of different investigational therapeutics for COVID-19 as compared to the control arm. In the first study of this platform trial reported here, remdesivir vs. placebo was studied.

Protection of trial subjects:

No additional measures beyond usual care of individuals hospitalised with COVID-19.

Background therapy:

none

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 23 March 2020 |
| 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 | Spain: 28 |
| Country: Number of subjects enrolled | United Kingdom: 46 |
| Country: Number of subjects enrolled | Denmark: 43 |
| Country: Number of subjects enrolled | Germany: 13 |
| Country: Number of subjects enrolled | Greece: 33 |
| Country: Number of subjects enrolled | Japan: 15 |
| Country: Number of subjects enrolled | Mexico: 10 |
| Country: Number of subjects enrolled | Singapore: 16 |

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Korea, Republic of: 21 |
| Country: Number of subjects enrolled | United States: 837 |
| Worldwide total number of subjects | 1062 |
| EEA total number of subjects | 117 |

Notes:

| Subjects enrolled per age group | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 678 |
| From 65 to 84 years | 340 |
| 85 years and over | 44 |

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from participating hospitals between 21 Feb 2020 and 20 Apr 2020

Pre-assignment

Screening details:

Hospitalized adults with COVID-19

Pre-assignment period milestones

| | |
|------------------------------|------|
| Number of subjects started | 1062 |
| Number of subjects completed | 1062 |

Period 1

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

Blinding implementation details:

Randomizer was given a treatment ID, which was sent to the pharmacy. The ID was decoded in the pharmacy. A saline placebo infusion was used. The infusion bag was covered with a colored sleeve to mask the slight different in color between the active product and placebo.

Arms

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

Arm description:

Normal saline given at equal volume on the same schedule

| | |
|--|-----------------------|
| Arm type | Placebo |
| Investigational medicinal product name | normal saline |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

A normal saline placebo will be given at an equal volume to the remdesivir infusion

| | |
|-----------|------------|
| Arm title | Remdesivir |
|-----------|------------|

Arm description:

200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10 days total course.

Remdesivir: Drug Remdesivir is a single diastereomer monophosphoramidate prodrug designed for the intracellular delivery of a modified adenine nucleoside analog GS-441524. In addition to the active ingredient, the lyophilized formulation of Remdesivir contains the following inactive ingredients: water for injection, sulfobutylether beta-cyclodextrin sodium (SBECD), and hydrochloric acid and/or sodium hydroxide.

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

| | |
|--|---------------------|
| Investigational medicinal product name | remdesivir |
| Investigational medicinal product code | |
| Other name | Veklury |
| Pharmaceutical forms | Powder for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10 days total course

| Number of subjects in period 1 | Placebo | Remdesivir |
|---------------------------------------|---------|------------|
| Started | 521 | 541 |
| Received treatment | 517 | 531 |
| Completed | 508 | 517 |
| Not completed | 13 | 24 |
| Physician decision | 1 | - |
| Consent withdrawn by subject | 7 | 9 |
| Adverse event, non-fatal | - | 4 |
| Transferred to another hospital | 1 | 1 |
| Enrolled but not treated | 4 | 10 |

Baseline characteristics

Reporting groups

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

Reporting group description:

Normal saline given at equal volume on the same schedule

| | |
|-----------------------|------------|
| Reporting group title | Remdesivir |
|-----------------------|------------|

Reporting group description:

200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10 days total course.

Remdesivir: Drug Remdesivir is a single diastereomer monophosphoramidate prodrug designed for the intracellular delivery of a modified adenine nucleoside analog GS-441524. In addition to the active ingredient, the lyophilized formulation of Remdesivir contains the following inactive ingredients: water for injection, sulfobutylether beta-cyclodextrin sodium (SBECD), and hydrochloric acid and/or sodium hydroxide.

| Reporting group values | Placebo | Remdesivir | Total |
|--|---------|------------|-------|
| Number of subjects | 521 | 541 | 1062 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 59.2 | 59.6 | |
| standard deviation | ± 15.4 | ± 14.6 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 189 | 189 | 378 |
| Male | 332 | 352 | 684 |

End points

End points reporting groups

| | |
|--|------------|
| Reporting group title | Placebo |
| Reporting group description: Normal saline given at equal volume on the same schedule | |
| Reporting group title | Remdesivir |
| Reporting group description: 200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10 days total course. | |
| Remdesivir: Drug Remdesivir is a single diastereomer monophosphoramidate prodrug designed for the intracellular delivery of a modified adenine nucleoside analog GS-441524. In addition to the active ingredient, the lyophilized formulation of Remdesivir contains the following inactive ingredients: water for injection, sulfobutylether beta-cyclodextrin sodium (SBECD), and hydrochloric acid and/or sodium hydroxide. | |

Primary: Time to recovery

| | |
|---|------------------|
| End point title | Time to recovery |
| End point description: Day of recovery is defined as the first day on which the subject satisfies one of the following three categories from the ordinal scale: 1) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 2) Not hospitalized, limitation on activities and/or requiring home oxygen; 3) Not hospitalized, no limitations on activities. | |
| End point type | Primary |
| End point timeframe: Day 1-29 (entire trial period) | |

| End point values | Placebo | Remdesivir | | |
|----------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 521 | 541 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 15 (13 to 18) | 10 (9 to 11) | | |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Main analysis |
| Comparison groups | Placebo v Remdesivir |
| Number of subjects included in analysis | 1062 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 1.29 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.12 |
| upper limit | 1.49 |

Secondary: Mean change in ordinal scale

| | |
|--|------------------------------|
| End point title | Mean change in ordinal scale |
| End point description: | |
| The ordinal scale is an assessment of the clinical status at the first assessment of a given study day. The scale is as follows: 8) Death; 7) Hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 6) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 5) Hospitalized, requiring supplemental oxygen; 4) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 3) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 2) Not hospitalized, limitation on activities and/or requiring home oxygen; 1) Not hospitalized, no limitations on activities. A positive change indicates a worsening and a negative change is an improvement. | |
| End point type | Secondary |
| End point timeframe: | |
| Through Day 29. The ordinal scale was measured at Day 1, 3, 5, 8, 11, 15, 22, and 29 | |

| End point values | Placebo | Remdesivir | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 518 | 533 | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 2.3) | -2.3 (± 2.6) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants at each clinical status using ordinal scale at Day 15

| | |
|--|--|
| End point title | Percentage of participants at each clinical status using ordinal scale at Day 15 |
| End point description: | |
| The ordinal scale is an assessment of the clinical status at the first assessment of a given study day. The scale is as follows: 8) Death; 7) Hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 6) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 5) Hospitalized, requiring supplemental oxygen; 4) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 3) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 2) Not hospitalized, limitation on activities and/or requiring home oxygen; 1) Not hospitalized, no limitations on activities | |
| End point type | Secondary |
| End point timeframe: | |
| At Day 15 | |

| End point values | Placebo | Remdesivir | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 521 | 541 | | |
| Units: percent | | | | |
| number (confidence interval 95%) | | | | |
| Death at or before study visit | 11 (9 to 14) | 6 (5 to 9) | | |
| Hospitalized, on invasive mech. vent. or ECMO | 22 (19 to 26) | 15 (13 to 19) | | |
| hospitalized, on non-invasive vent./high flow O2 | 4 (3 to 6) | 4 (3 to 6) | | |
| Hospitalized, requiring supplemental O2 | 11 (9 to 14) | 10 (8 to 13) | | |
| Hospitalized, not on O2, requiring ongoing care | 6 (5 to 9) | 7 (5 to 9) | | |
| Hospitalized, not requiring O2, no longer req care | 2 (1 to 3) | 3 (2 to 4) | | |
| Not hospitalized, limit on activities/req home O2 | 17 (14 to 21) | 19 (16 to 22) | | |
| Not hospitalized, no limitations on activities | 22 (19 to 26) | 29 (25 to 33) | | |
| No clinical status score reported - Hospitalized | 0 (0 to 1) | 0 (0 to 1) | | |
| No clinical status score reported - Discharged | 2 (1 to 3) | 2 (1 to 4) | | |
| No clinical status score reported - Discontinued | 3 (2 to 4) | 5 (3 to 7) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mortality

| | |
|--|-----------|
| End point title | Mortality |
| End point description: | |
| The mortality rate was estimated as the percentage of participants who died by study Day 29. | |
| End point type | Secondary |
| End point timeframe: | |
| Entire trial (through day 29) | |

| End point values | Placebo | Remdesivir | | |
|----------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 521 | 541 | | |
| Units: perc | | | | |
| number (confidence interval 95%) | 15 (12 to 19) | 11 (9 to 15) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Days 1-29 (entire trial)

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 23 |
|--------------------|----|

Reporting groups

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

Reporting group description:

Normal saline given at equal volume on the same schedule

| | |
|-----------------------|------------|
| Reporting group title | Remdesivir |
|-----------------------|------------|

Reporting group description:

200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10 days total course.

Remdesivir: Drug Remdesivir is a single diastereomer monophosphoramidate prodrug designed for the intracellular delivery of a modified adenine nucleoside analog GS-441524. In addition to the active ingredient, the lyophilized formulation of Remdesivir contains the following inactive ingredients: water for injection, sulfobutylether beta-cyclodextrin sodium (SBECD), and hydrochloric acid and/or sodium hydroxide.

| Serious adverse events | Placebo | Remdesivir | |
|---|--------------------|--------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 163 / 516 (31.59%) | 131 / 532 (24.62%) | |
| number of deaths (all causes) | 77 | 59 | |
| number of deaths resulting from adverse events | | | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 7 / 516 (1.36%) | 4 / 532 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Shock | | | |
| subjects affected / exposed | 4 / 516 (0.78%) | 5 / 532 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|--|-----------------|-----------------|--|
| Embolism venous | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Endotracheal intubation | | | |
| subjects affected / exposed | 9 / 516 (1.74%) | 6 / 532 (1.13%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mechanical ventilation | | | |
| subjects affected / exposed | 3 / 516 (0.58%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 3 / 516 (0.58%) | 5 / 532 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 4 | |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-------------------|------------------|--|
| Death | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory failure | | | |
| subjects affected / exposed | 58 / 516 (11.24%) | 35 / 532 (6.58%) | |
| occurrences causally related to treatment / all | 0 / 59 | 0 / 36 | |
| deaths causally related to treatment / all | 0 / 28 | 0 / 20 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 14 / 516 (2.71%) | 8 / 532 (1.50%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 6 | 0 / 2 | |
| Respiratory distress | | | |
| subjects affected / exposed | 11 / 516 (2.13%) | 6 / 532 (1.13%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 2 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 5 / 516 (0.97%) | 7 / 532 (1.32%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 4 | |
| Pneumothorax | | | |
| subjects affected / exposed | 5 / 516 (0.97%) | 5 / 532 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 4 / 516 (0.78%) | 5 / 532 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Hypoxia | | | |
| subjects affected / exposed | 4 / 516 (0.78%) | 4 / 532 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 4 / 532 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 3 / 532 (0.56%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory disorder | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary haemorrhage | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Psychiatric disorders | | | |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic disorder | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Glomerular filtration rate decreased | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 5 / 532 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oxygen saturation decreased | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|--|-----------------|------------------|--|
| Procedural pneumothorax subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 7 / 516 (1.36%) | 10 / 532 (1.88%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 7 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 5 / 532 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 3 / 516 (0.58%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 4 / 516 (0.78%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 3 / 516 (0.58%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 2 / 532 (0.38%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 516 (0.19%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Palpitations | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulseless electrical activity | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac tamponade | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 516 (0.19%) | 3 / 532 (0.56%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 2 / 532 (0.38%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic transformation stroke | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intensive care unit acquired weakness | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 3 / 532 (0.56%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Duodenal perforation | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal perforation | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Haematemesis | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic hepatitis | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|------------------|-----------------|--|
| Subcutaneous emphysema | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 12 / 516 (2.33%) | 7 / 532 (1.32%) | |
| occurrences causally related to treatment / all | 1 / 12 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 5 / 516 (0.97%) | 2 / 532 (0.38%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 3 / 516 (0.58%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myalgia | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Septic shock | | | |

| | | | |
|---|------------------|-----------------|--|
| subjects affected / exposed | 15 / 516 (2.91%) | 8 / 532 (1.50%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 3 | |
| COVID-19 | | | |
| subjects affected / exposed | 5 / 516 (0.97%) | 2 / 532 (0.38%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Bacteraemia | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Sepsis | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 2 / 516 (0.39%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter bacteraemia | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious pleural effusion | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial sepsis | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis bacterial | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Acidosis | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 516 (0.00%) | 1 / 532 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 516 (0.19%) | 0 / 532 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Placebo | Remdesivir | |
|---|--------------------|--------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 295 / 516 (57.17%) | 276 / 532 (51.88%) | |
| Investigations | | | |
| Glomerular filtration rate decreased | | | |
| subjects affected / exposed | 74 / 516 (14.34%) | 55 / 532 (10.34%) | |
| occurrences (all) | 81 | 59 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 62 / 516 (12.02%) | 48 / 532 (9.02%) | |
| occurrences (all) | 69 | 51 | |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 54 / 516 (10.47%) | 44 / 532 (8.27%) | |
| occurrences (all) | 63 | 56 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 36 / 516 (6.98%) | 31 / 532 (5.83%) | |
| occurrences (all) | 41 | 33 | |
| Blood glucose increased | | | |
| subjects affected / exposed | 27 / 516 (5.23%) | 39 / 532 (7.33%) | |
| occurrences (all) | 31 | 45 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 33 / 516 (6.40%) | 18 / 532 (3.38%) | |
| occurrences (all) | 35 | 19 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |

| | | | |
|--|-------------------|------------------|--|
| subjects affected / exposed | 52 / 516 (10.08%) | 42 / 532 (7.89%) | |
| occurrences (all) | 58 | 52 | |
| Lymphopenia | | | |
| subjects affected / exposed | 30 / 516 (5.81%) | 13 / 532 (2.44%) | |
| occurrences (all) | 34 | 15 | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 32 / 516 (6.20%) | 38 / 532 (7.14%) | |
| occurrences (all) | 37 | 52 | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 34 / 516 (6.59%) | 34 / 532 (6.39%) | |
| occurrences (all) | 43 | 36 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------|--|
| 26 May 2020 | After remdesivir was shown to be effective in ACTT-1, this platform protocol was amended to ACTT-2, which compared baricitanib vs. placebo on a background of remdesivir as standard of care. The results of ACTT-2 are reported in an attachment. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/32445440>