Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Salama C, Han J, Yau L, et al. Tocilizumab in patients hospitalized with Covid-19 pneumonia. N Engl J Med. DOI: 10.1056/NEJMoa2030340

SUPPLEMENTARY APPENDIX

Contents

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Methods

Study site selection

Countries were selected for participation based on the evolving epidemiology of the pandemic and emerging COVID-19 hot spots. The countries selected also identified underserved patient populations with a high level of unmet need. Site selection was based on case load and response to a questionnaire regarding patient population served and ability to adhere to the protocol (i.e. availability of staff, laboratory facilities and resources).

Contract research organization

The study complied with the requirements of the ICH E2A guideline (Clinical Safety Data Management: Definitions and Standards for Expedited Reporting). Site visits were conducted remotely by the Sponsor or an authorized representative for inspection of study data, patients' medical records, and electronic case report forms (eCRFs). The investigator permitted national and local health authorities; Sponsor monitors, representatives, and collaborators; and the institutional review boards/ethics committees to inspect facilities and records relevant to this study.

Blinding at the study site

A site blinding plan was established at each site to identify which personnel would be blinded or unblinded at a site level. A pharmacy manual and specific training in addition to completion of a site blinding plan was provided to each site. Each site had an unblinded pharmacist that randomized the patient and prepared and labeled study medication in the same method for both tocilizumab and placebo. The remainder of the study team was blinded to treatment assignment. There was no communication during the study between unblinded and blinded members. In addition, there was an unblinded medical monitor available to answer questions from the unblinded site staff. Placebo was not provided and consisted of an unaltered saline infusion bag, the same as would be used to prepare tocilizumab. The volume of tocilizumab diluted in saline appears colorless and matches saline.

Source data verification

Due to the pandemic situation, access to hospitals is restricted; therefore, only remote data monitoring was performed for this study. Study monitors performed ongoing remote data review to confirm that critical protocol data (ie, source data) entered into the eCRFs by authorized site personnel were accurate and complete. Sites were asked to implement a quality control step of a second person reviewing the data entry in the eCRF where possible.

Monitors had increased contact with sites, for some up to once daily due to rapid enrollments. An internal central site monitoring tool was built based on SAS programs and Spotfire analytics tools. Specific reports were developed to review critical variables. The Dashboard was used to rapidly identify study trends and site-specific issues in real time; this was relayed to monitors who could rapidly resolve issues.

Internal Monitoring Committee

An Internal Monitoring Committee (IMC) consisting of Sponsor representatives who were not directly involved in the study management team was incorporated for this study. Through review and summary of unblinded study data, the IMC helped the Study Medical Director minimize patient exposure to unusual risk. The IMC met once on July 13, 2020, to review unblinded summaries of accumulated safety data of the study and concluded that there were no safety findings and the study could proceed as planned.

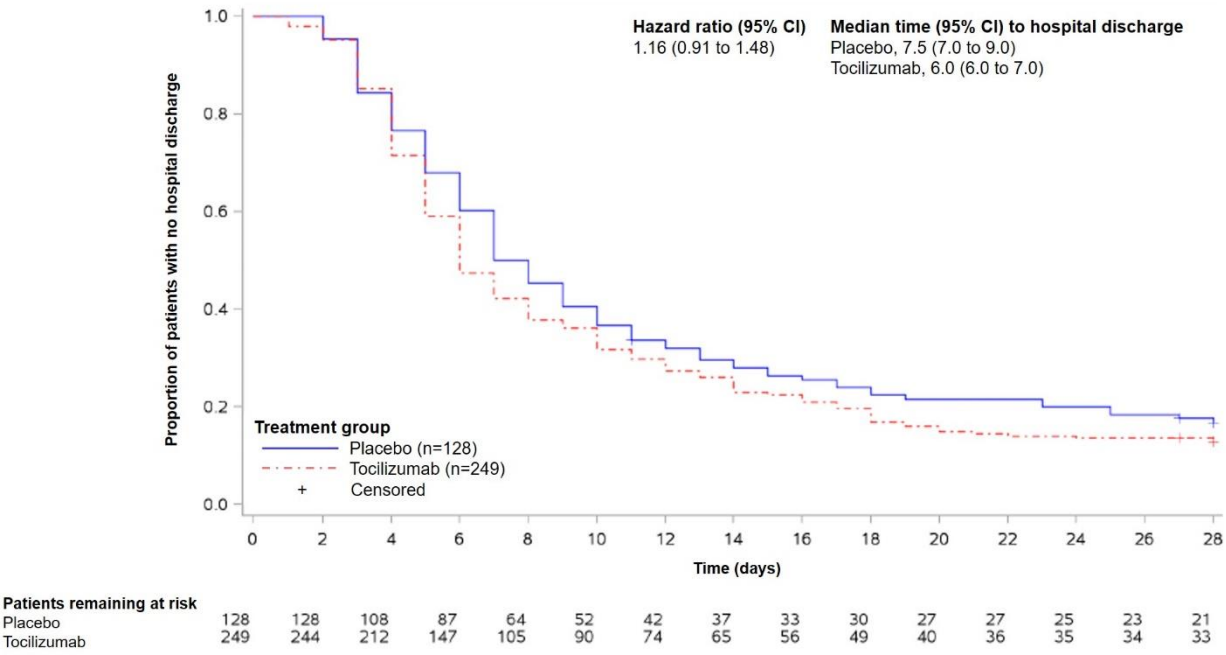
Competing risk analyses

For the secondary efficacy endpoints, time to hospital discharge/ready for discharge and time to improvement in clinical status, the cumulative incidence function plots for both death and the endpoint of interest were produced using the non-parametric Aalen–Johansen estimator, where death prior to experiencing the event was treated as a competing risk. The hazard ratio and its 95% confidence interval (CI) between treatment arms were estimated by the Fine and Gray's proportional subdistribution hazards model stratified by age (≤60, >60 years).[1]

Subgroup analyses

For the analysis of the primary efficacy endpoint, time to requiring mechanical ventilation or death up to Day 28, by subgroups, the unstratified Cox proportional hazard model was used to estimate the hazard ratio and 95% confidence interval (CI) between treatment arms.

Figure S1. Kaplan-Meier plot of time to hospital discharge/ready for discharge up to Day 28* (modified intent-to-treat population)

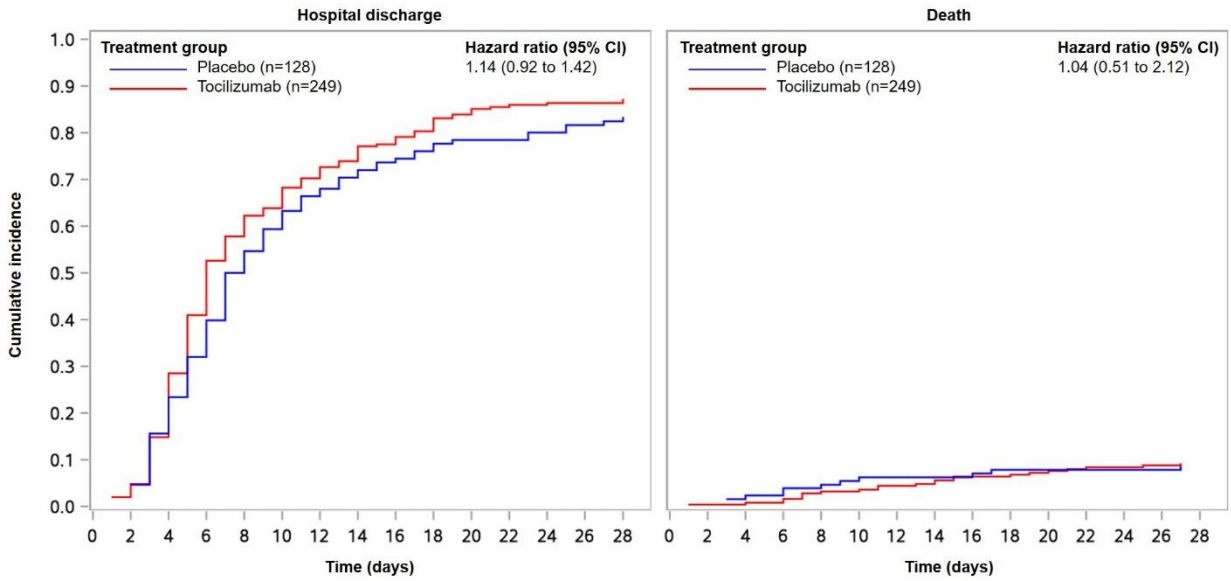


Significance testing was performed hierarchically to control for study-wide type I error rate at a 5% significance level. P value not presented because first secondary endpoint failed to reach significance.

The stratified Cox proportional hazard model was used to estimate the hazard ratio and 95% confidence interval (CI) between treatment arms.

*Patients who died were censored at Day 28 and patients without any events on or prior to Day 28 were censored at the earlier date of Day 28 and date of last ordinal scale assessment.

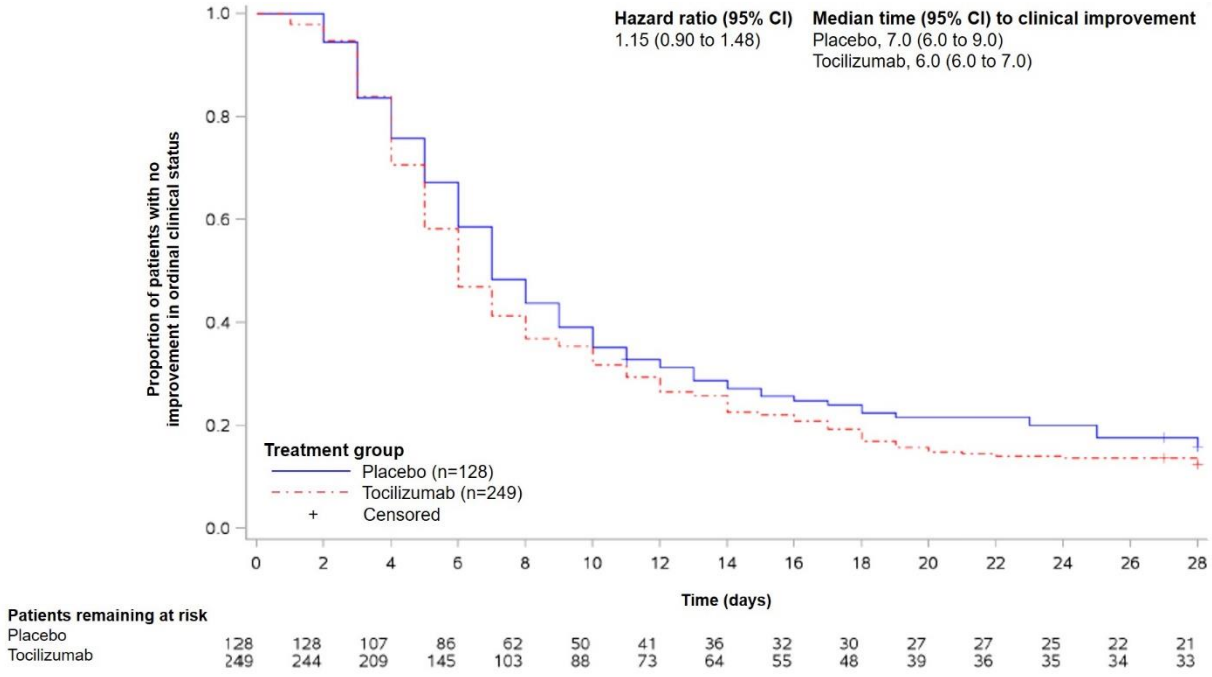
Figure S2: Competing risk analysis: cumulative incidence function plot of time to hospital discharge or ready for discharge up to Day 28 (modified intent-to-treat population)



Event of interest is defined as hospital discharge or ready for discharge before death. Competing risk is defined as death without the event of interest.

Cumulative incidence function plots were estimated by the non-parametric Aalen–Johansen estimator, where death prior to hospital discharge/ready for discharge was treated as a competing risk. The hazard ratio and its 95% CI between the treatment arms were estimated by the Fine and Gray's proportional subdistribution hazards model stratified by age (≤60, >60 years).

Figure S3. Kaplan-Meier plot of time to improvement in ordinal clinical status* up to Day 28† (modified intent-to-treat population)



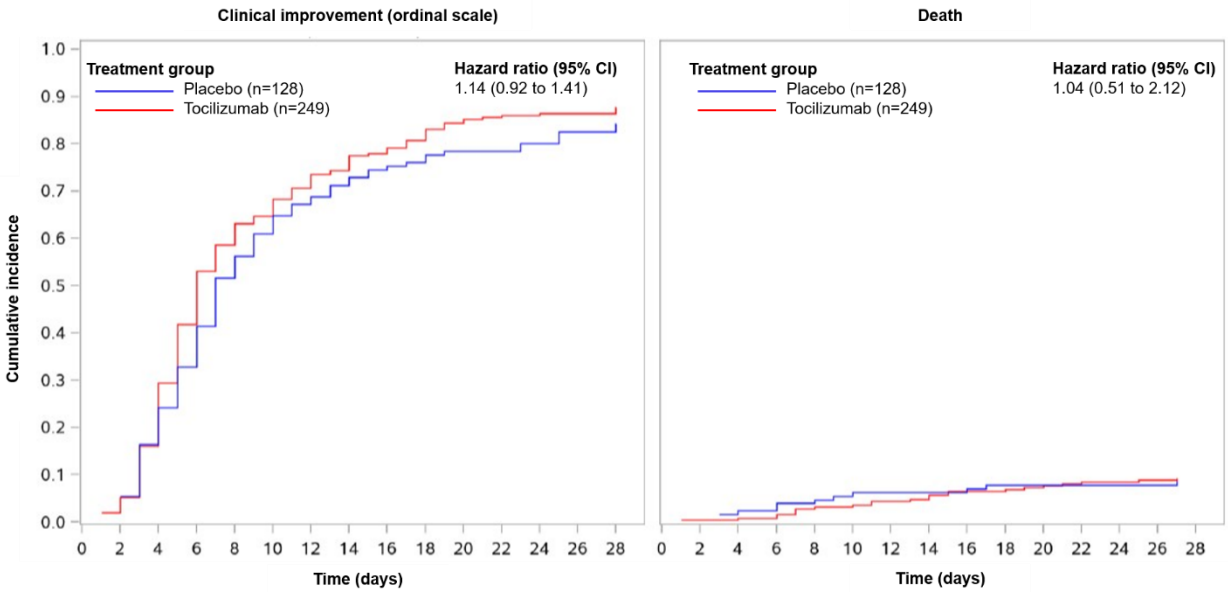
Significance testing was performed hierarchically to control for study-wide type I error rate at a 5% significance level. P value not presented because first secondary endpoint failed to reach significance.

The stratified Cox proportional hazard model was used to estimate the hazard ratio and 95% confidence interval (CI) between treatment arms.

*7-category ordinal scale: 1, discharged (or ready for discharge as evidenced by normal body temperature and respiratory rate, and stable oxygen saturation on ambient air or ≤2L supplemental oxygen); 2, non–intensive care unit (ICU) hospital ward (or ready for hospital ward), not requiring supplemental oxygen; 3, non–ICU hospital ward (or ready for hospital ward), requiring supplemental oxygen; 4, ICU or non–ICU hospital ward, requiring noninvasive ventilation or high-flow oxygen; 5, ICU, requiring intubation and mechanical ventilation; 6, ICU, requiring extracorporeal membrane oxygenation or mechanical ventilation and additional organ support; 7, death.

†Patients who died were censored at Day 28 and patients without any events on or prior to Day 28 were censored at the earlier date of Day 28 and date of last ordinal scale assessment.

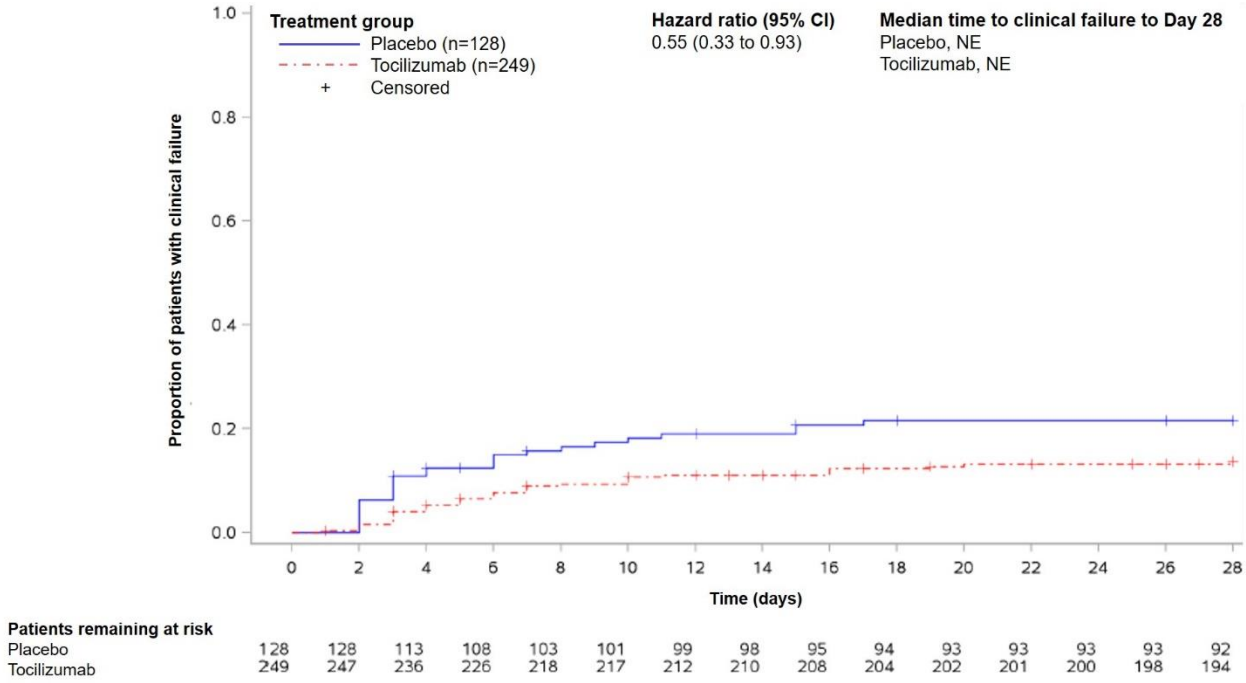
Figure S4: Competing risk analysis: cumulative incidence function plot of time to improvement in ordinal clinical status up to Day 28 (modified intent-to-treat population)



Event of interest is defined as improvement in ordinal clinical status before death. Competing risk is defined as death without the event of interest.

Cumulative incidence function plots were estimated by the non-parametric Aalen–Johansen estimator, where death prior to clinical improvement based on ordinal scale was treated as a competing risk. The hazard ratio and its 95% CI between the treatment arms were estimated by the Fine and Gray's proportional subdistribution hazards model stratified by age (≤60, >60 years).

Figure S5. Cumulative proportion plot of time to clinical failure up to Day 28* (modified intent-to-treat population)



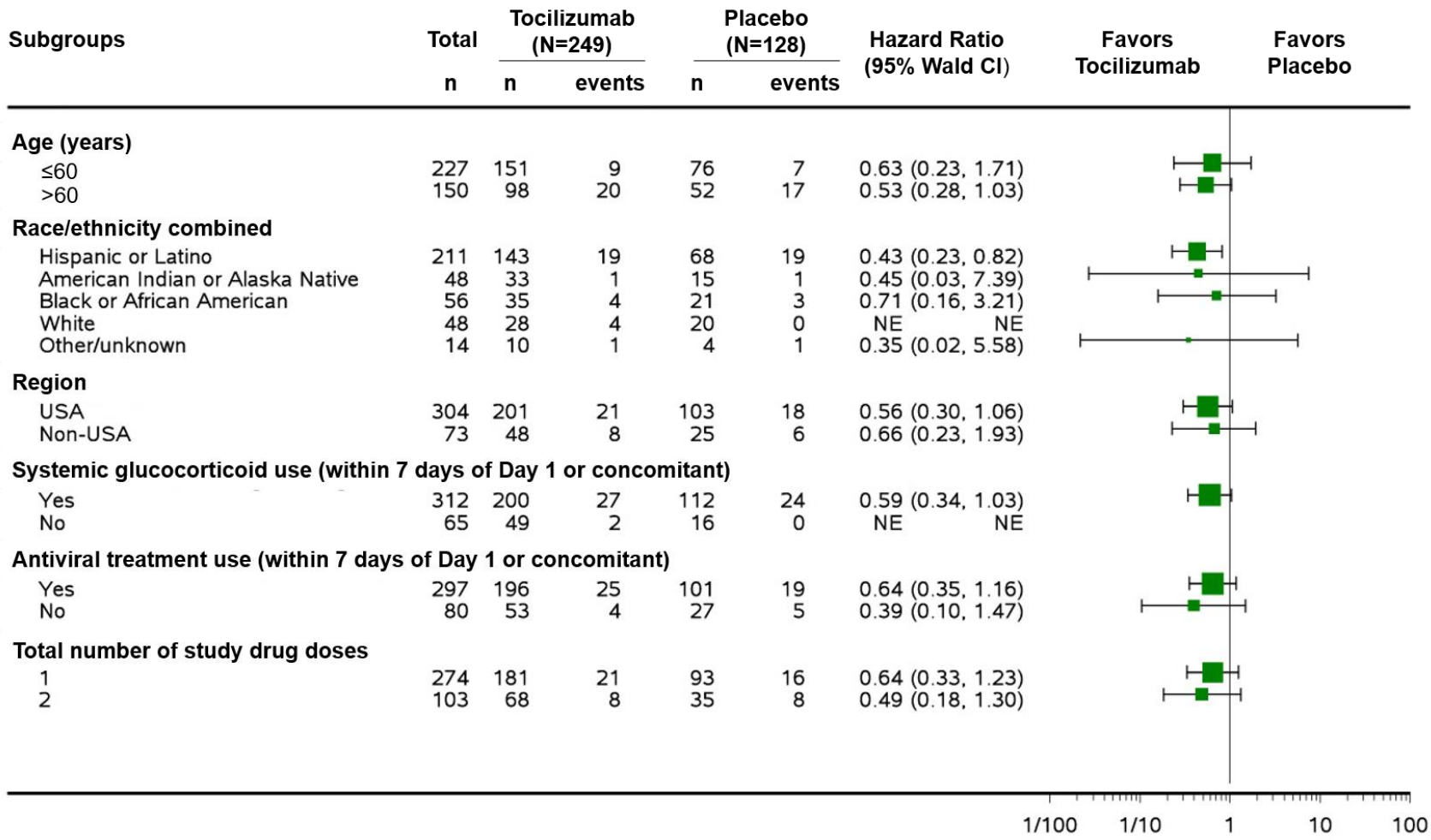
NE, not estimable.

Significance testing was performed hierarchically to control for study-wide type I error rate at a 5% significance level. P value not presented because first secondary endpoint failed to reach significance.

The stratified Cox proportional hazard model was used to estimate the hazard ratio and 95% confidence interval (CI) between treatment arms.

*Patients not experiencing any clinical failure on or prior to Day 28 were censored at the last contact date or Day 28, whichever was earlier.

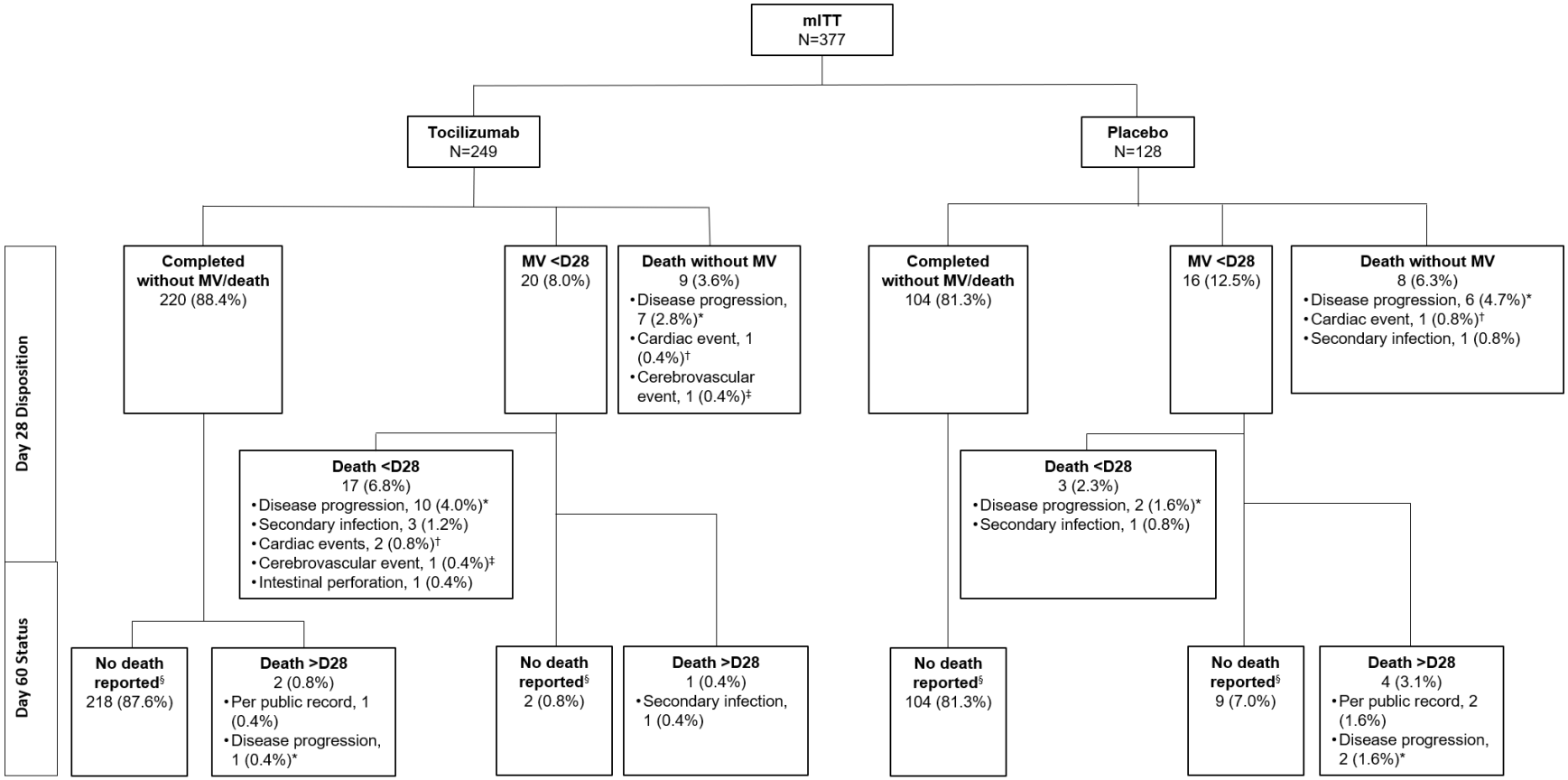
Figure S6. Forest plot of hazard ratio for time to death or requiring mechanical ventilation up to Day 28 by subgroup (modified intent-to-treat population)



NE, not estimable due to no events observed in the placebo arm.

The unstratified Cox proportional hazard model was used to estimate the hazard ratio and 95% confidence interval (CI) between treatment arms. Unstratified hazard ratios are displayed. Hazard ratio <1 favors tocilizumab.

Figure S7. Fatal events observed through Day 60



Data are represented as no. (%) unless otherwise indicated

D, day; mITT, modified intent to treat; MV, mechanical ventilation.

*Disease progression included COVID-19 pneumonia, respiratory failure, acute respiratory distress syndrome, acute respiratory failure, and respiratory distress.

†Cardiac events included the following preferred terms: acute myocardial infarction, cardiac arrest, and myocardial infarction.

‡Cerebrovascular events included the following preferred terms: brain stem stroke and cerebrovascular accident.

§No death reported through adverse events reporting or reporting of deaths by public records.

Table S1. 7-Category ordinal scale

Category	Clinical Status
1	Discharged (or ready for discharge as evidenced by normal body temperature and respiratory rate, and stable oxygen saturation on ambient air or ≤2L supplemental oxygen)
2	Non–ICU hospital ward (or ready for hospital ward), not requiring supplemental oxygen
3	Non–ICU hospital ward (or ready for hospital ward), requiring supplemental oxygen
4	ICU or non–ICU hospital ward, requiring noninvasive ventilation or high-flow oxygen
5	ICU, Requiring intubation and mechanical ventilation
6	ICU, requiring extracorporeal membrane oxygenation or mechanical ventilation and additional organ support (e.g., vasopressors or renal replacement therapy)
7	Death

ICU, intensive care unit.

This ordinal scale has equivalent categories to those in the WHO ordinal scale for Covid-19[2] and was discussed and agreed upon with health authorities.

Table S2. Study enrollment by country (all randomized patients)

Country	Active Sites, n	Patients, n
Brazil	6	11
Kenya	2	10
Mexico	2	11
Peru	5	29
South Africa	3	12
United States	45	315*

*Excludes 1 patient who was randomized prior to local institutional review board approval of study site.

Table S3. Study drug exposure (safety population)

	Tocilizumab N=250	**Placebo N=127**	**All Patients N=377**
Total number of doses administered, no. (%)			
1	182 (72.8)	92 (72.4)	274 (72.7)
2	68 (27.2)	35 (27.6)	103 (27.3)
Time from first dose to second dose, hours*			
No. of patients	51	23	74
Mean (SD)	19.26 (3.40)	20.78 (6.20)	19.73 (4.47)
Median (range)	20.15 (10.2-26.2)	20.15 (10.3-43.9)	20.15 (10.2-43.9)

*Time from first dose to second dose was calculated as the start time of the second dose minus the end time of the first dose. This measure was not calculated for patients with missing time information in dosing records.

Table S4. Additional baseline patient demographics and disease characteristics (modified intent-to-treat population)*

	Tocilizumab N=249	**Placebo N=128**	**All Patients N=377**
Female	99 (39.8)	55 (43.0)	154 (40.8)
Age group, no. (%), years			
18-64	178 (71.5)	93 (72.7)	271 (71.9)
65-84	70 (28.1)	33 (25.8)	103 (27.3)
≥ 85	1 (0.4)	2 (1.6)	3 (0.8)
Weight, mean (SD), kg	89.57 (23.73)	94.44 (25.95)	91.22 (24.58)
Smoking history, no. (%)			
Never	192 (77.1)	99 (77. 3)	291 (77.2)
Current	16 (6.4)	6 (4.7)	22 (5.8)
Former	41 (16.5)	23 (18.0)	64 (17.0)
Elevated CRP[†], no./observed n (%)	186/227 (81.9)	104/120 (86.7)	290/347 (83.6)
hs-CRP, mg/L, no.	41	21	62
Median (range)	68.25 (0.1-494.7)	76.40 (2.0-290.7)	70.85 (0.1-494.7)
Days from first Covid-19 symptom at baseline, no.	248	127	375
Median (range)	8.0 (0.0-31.0)	8.0 (0.0-36.0)	8.0 (0.0-36.0)
Days from Covid-19 diagnosis, median (range)	1.0 (0.0-14.0)	2.0 (0.0-12.0)	2.0 (0.0-14.0)
ICU admission at baseline, no. (%)	36 (14.5)	22 (17.2)	58 (15.4)
Comorbidities, no. (%)[‡§]	250	127	377
Patients with ≥1 comorbidity	191 (76.4)	96 (75.6)	287 (76.1)
Asthma	27 (10.8)	16 (12.6)	43 (11.4)

Atrial fibrillation	6 (2.4)	6 (4.7)	12 (3.2)
Chronic obstructive pulmonary disease	12 (4.8)	5 (3.9)	17 (4.5)
Diabetes	105 (42.0)	48 (37.8)	153 (40.6)
Hyperlipidemia	70 (28.0)	34 (26.8)	104 (27.6)
Hypertension	119 (47.6)	63 (49.6)	182 (48.3)
Myocardial infarction	4 (1.6)	3 (2.4)	7 (1.9)
Obesity	54 (21.6)	38 (29.9)	92 (24.4)
Stroke	8 (3.2)	3 (2.4)	11 (2.9)

CRP, C-reactive protein; hs; high sensitivity; ICU, intensive care unit.

*Unless otherwise indicated.

[†]Patients with CRP >50 mg/L or hs-CRP >3 mg/L at baseline.

[‡]Safety population.

[§]Included both resolved and ongoing comorbidities. Patients could have >1 condition.

Table S5. Proportion of patients who received systemic corticosteroids and antivirals within 7 days prior to first dose of study drug or during the study (modified intent-to-treat population)

Drug, no. (%)	**Tocilizumab N=249**	**Placebo N=128**	**All Patients N=377**
Systemic corticosteroid	200 (80.3)	112 (87.5)	312 (82.8)
Antiviral	196 (78.7)	101 (78.9)	297 (78.8)

Table S6. Proportion of patients who received dexamethasone and remdesivir within 7 days prior to first dose of study drug or during the study (modified intent-to-treat population)

Drug, no. (%)	**Tocilizumab N=249**	**Placebo N=128**	**All Patients N=377**
Dexamethasone	138 (55.4)	86 (67.2)	224 (59.4)
Remdesivir	131 (52.6)	75 (58.6)	206 (54.6)

Table S7. Competing risk analysis: analysis of time to hospital discharge or ready for discharge up to Day 28 (modified intent-to-treat population)

			Comparison	
	Tocilizumab N=249	**Placebo N=128**	**Hazard ratio* (95% CI)**	**P value (from Gray's test)†**
Time to hospital discharge or ready for discharge				
Cumulative incidence by Day 28 (95% CI)	0.87 (0.82-0.91)	0.83 (0.76-0.89)	1.14 (0.92-1.42)	0.2548
Death prior to hospital discharge (as competing risk)				
Cumulative incidence by Day 28 (95% CI)	0.09 (0.06-0.13)	0.09 (0.05-0.14)	1.04 (0.51-2.12)	0.9327

*Fine and Gray's proportional subdistribution hazards model was used to estimate the hazard ratio. Age (≤60, >60 years) was used as a stratification factor.

†Gray's test was used for comparison of treatment-specific cumulative incidence functions.

Table S8. Competing risk analysis: analysis of time to improvement in ordinal clinical status up to Day 28 (modified intent-to-treat population)

			Comparison	
	Tocilizumab N=249	Placebo N=128	Hazard ratio* (95% CI)	P value (from Gray's test)†
Time to improvement in ordinal clinical status				
Cumulative incidence by Day 28 (95% CI)	0.88 (0.83-0.91)	0.84 (0.77-0.90)	1.14 (0.92-1.41)	0.2698
Death prior to improvement in ordinal clinical status (as competing risk)				
Cumulative incidence by Day 28 (95% CI)	0.09 (0.06-0.13)	0.09 (0.05-0.14)	1.04 (0.51-2.12)	0.9348

*Fine and Gray's proportional subdistribution hazards model was used to estimate the hazard ratio. Age (≤60, >60 years) was used as a stratification factor.

†Gray's test was used for comparison of treatment-specific cumulative incidence functions.

Table S9. Acute kidney injury through Day 60 (safety population)

	Tocilizumab N=250	**Placebo N=127**	**All Patients N=377**
Acute kidney injury adverse event	4 (1.6)	4 (3.1)	8 (2.1)
Acute kidney injury serious adverse event	1 (0.4)	3 (2.4)	4 (1.1)

Table S10. Deaths between Day 28 and Day 60 (safety population)

	Tocilizumab N=250	**Placebo N=127**	**All Patients N=377**
Total number of deaths, no. of patients (%)	29 (11.6%)	15 (11.8%)	44 (11.7%)
Days from first study drug administration, no. of patients			
≤28 days	26	11	37
>28 days	3	4	7

Deaths were taken from adverse event records, ordinal scale reporting, post-study reporting of deaths, and public records.

References

1. Fine J, & Gray R. A Proportional Hazards Model for the Subdistribution of a Competing Risk. *Journal of the American Statistical Association*, 1999;94(446):496-509. doi:10.2307/2670170
2. World Health Organization. WHO R&D Blueprint novel Coronavirus COVID-19 Therapeutic Trial Synopsis. https://www.who.int/blueprint/priority-diseases/key-action/COVID-19_Treatment_Trial_Design_Master_Protocol_synopsis_Final_18022020.pdf. Accessed October 23, 2020.