Supplementary Appendix

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

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Effect of Dexamethasone in Hospitalized Patients with COVID-19

SUPPLEMENTARY APPENDIX

RECOVERY Collaborative Group

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Supplementary Methods

Study organization

The RECOVERY trial is an investigator-initiated, individually randomized, open-label, controlled trial to evaluate the efficacy and safety of a range of putative treatments in patients hospitalized with COVID-19. The protocol is available at NEJM.org. The trial was conducted at 176 National Health Service (NHS) hospital organizations in the United Kingdom. The trial was coordinated by a team drawn from the Clinical Trial Service Unit and the National Perinatal Epidemiology Clinical Trials Unit within the Nuffield Department of Population Health at University of Oxford, the trial sponsor. Support for local site activities was provided by the National Institute for Health Research Clinical Research Network.

Treatment supply to local sites was supported by National Health Service (NHS) England and Public Health England. Access to relevant routine health care and registry data was supported by NHS DigiTrials, the Intensive Care National Audit and Research Centre, Public Health Scotland, National Records Service of Scotland, and the Secure Anonymised Information Linkage (SAIL) at University of Swansea.

Protocol changes

RECOVERY is a randomized trial among patients hospitalized for COVID-19. All eligible patients receive usual standard of care in the participating hospital and are randomly allocated between no additional treatment and one of several active treatment arms. Over time, additional treatment arms have been added (see Table). In version 4.0 of the protocol, a second randomization was introduced for those trial participants with hypoxia (oxygen saturation <92% on air or receiving oxygen) and inflammation (C-reactive protein ≥75 mg/dL), comparing the addition of tocilizumab vs. control on top of the treatment assigned in the first randomization. In version 6.0, a factorial design was introduced to the first randomization such that participants were also randomized to convalescent plasma vs. no additional treatment. As outlined in the protocol, if one or more of the active treatments was not available at the hospital or is believed, by the attending clinician, to be contraindicated (or definitely indicated) for the specific patient, then random allocation was between the remaining treatment arms.

The original and final protocol are included in the supplementary material to this publication, together with summaries of the changes made.

Table. Protocol changes to treatment comparisons

Protocol version	Date	Randomization	Treatment arms
1.0	13-Mar-2020	Main (part A)	No additional treatment Lopinavir-ritonavir Low-dose corticosteroid Nebulised Interferon-ß-1a (never activated)
2.0	23-Mar-2020	Main (part A)	No additional treatment Lopinavir-ritonavir Low-dose corticosteroid Hydroxychloroquine
3.0	07-Apr-2020	Main (part A)	No additional treatment Lopinavir-ritonavir Low-dose corticosteroid Hydroxychloroquine Azithromycin

Protocol version	Date	Randomization	Treatment arms
4.0	14-Apr-2020	Main (part A)	No additional treatment Lopinavir-ritonavir Low-dose corticosteroid Hydroxychloroquine Azithromycin
		Second[a]	No additional treatment Tocilizumab
5.0	24-Apr-2020	-	(no change – extension to children <18 years old)
6.0	14-May-2020	Main (part A)	No additional treatment Lopinavir-ritonavir Low-dose corticosteroid[b] Hydroxychloroquine[c] Azithromycin
		Main (part B factorial)	No additional treatment Convalescent plasma
		Second[a]	No additional treatment Tocilizumab

[a] for patients with (a) oxygen saturation <92% on air or requiring oxygen or children with significant systemic disease with persistent pyrexia; and (b) C-reactive protein ≥75 md/dL)
[b] enrolment of adults ceased 8 June 2020 as more than 2,000 patients had been recruited to the active arm
[c] enrolment ceased 5 June 2020 when the Data Monitoring Committee advised that the Chief Investigators review the unblinded data.

Supplementary statistical methods

Sample size

As stated in the protocol, appropriate sample sizes could not be estimated when the trial was being planned at the start of the COVID-19 pandemic. As the trial progressed, the Trial Steering Committee, blinded to the results of the study treatment comparisons, formed the view that sufficient patients should be enrolled to each comparison to provide at least 90% power at two-sided P=0.01 to detect a proportional reduction in 28-day mortality of one-fifth. Thus, if 28-day mortality was 20% then a comparison of at least 2000 participants allocated to active drug and 4000 to usual care alone would suffice.

Baseline-predicted risk

Baseline−predicted risk of 28-day mortality was estimated through the formula 100 x exp(a)/(1 + exp(a)), where a = −1·23 − 2·85 (if age <50) − 2·03 (if age 50−59) − 1·21 (if age 60−69) − 0·51 (if age 70−79) + 0·42 (if male) − 0·34 (if >7 days since symptom onset) + 0·86 (if on oxygen only at randomization) + 2·18 (if on invasive mechanical ventilation at randomization) − 0·01 (if history of diabetes) + 0·22 (if history of heart disease) + 0·21 (if history of chronic lung disease) + 0·50 (if history of kidney disease). These regression coefficients were derived

from a multivariable logistic regression model using data from 10,702 trial participants who had complete 28-day mortality follow-up data by 22 June 2020. The regression model additionally adjusted for treatment allocation (with usual care designated the reference category) and for all possible two-way interactions between the above baseline characteristics and treatment allocation. These additional terms were ignored when calculating baseline-predicted risk, however, in order to ensure that the estimates corresponded to risk *if assigned usual care*. Patients were then subdivided into three approximately equally-sized groups (across all RECOVERY participants) on the basis of their predicted risk: <30%, ≥30% to <45%, and ≥45%.

Ascertainment and classification of study outcomes
Information on baseline characteristics and study outcomes was collected through a combination of electronic case report forms (see below) completed by members of the local research team at each participating hospital and linkage to National Health Service, clinical audit, and other relevant health records. Full details are provided in the RECOVERY Definition and Derivation of Baseline Characteristics and Outcomes Document which is included with the trial protocol and statistical analysis plan at www.nejm.org.

Randomization form

The Randomization form (shown below) was completed by trained study staff. It collected baseline information about the participant (including demographics, COVID-19 history, comorbidities and suitability for the study treatments) and availability of the study treatments. Once completed and electronically signed, the treatment allocation was displayed.

The following modifications were made to the Randomization form during the trial:

Randomization form version	**Date of release**	**Major modifications from previous version**
1.0	19-Mar-20	Initial version (protocol V1.0)
2.0	25-Mar-20	For protocol V2.0 • Hydroxycholoroquine added as treatment • Known long QT syndrome added to comorbidities • Severe depression removed from comorbidities
3.0	09-Apr-20	For protocol V3.0 • Azithromycin added as treatment • Suspected SARS-CoV-2 infection included in eligibility criteria
[Second randomization form introduced]	23-Apr-20	For protocol 4.0 • Eligibility criteria for second randomization • Tocilizumab vs control as treatment allocations
4.0	09-May-20	For protocol V5.0 • Age ≥18 years removed from eligibility criteria • Additional questions on child's age and weight added
5.0	21-May-20	For protocol V6.0 • Convalescent plasma added as treatment
6.0	28-May-20	Baseline use of remdesivir
7.0	05-Jun-20	Removal of hydroxychloroquine as treatment

Dexamethasone for COVID-19

RECOVERY

Randomised Evaluation of COVID-19 Therapy

Test version only (v6.03 - 27/05/20)

Randomisation Program

Call Freefone **0800 138 5451** to contact the RECOVERY team for **URGENT** problems using the Randomisation Program or for medical advice. All **NON-URGENT queries** should be emailed to **recoverytrial@ndph.ox.ac.uk**

Logged in as: **Barts Health NHS Trust**

Section A: Baseline and Eligibility

Date and time of randomisation: 27 May 2020 11:17

Treating clinician

A1. Name of treating clinician

Patient details

A2. Patient surname

Patient forename

A3. NHS number ☐ Tick if not available

A4. What is the patient's date of birth? / /

A5. What is the patient's sex?

Inclusion criteria

A6. Has consent been taken in line with the protocol?
If answer is No patient cannot be enrolled in the study

A7. Does the patient have proven or suspected SARS-CoV-2 infection?
If answer is No patient cannot be enrolled in the study

A8. Does the patient have any medical history that might, in the opinion of the attending clinician, put the patient at significant risk if they were to participate in the trial?

A8B. Is the patient willing to receive convalescent plasma?

A9. COVID-19 symptom onset date: / /

A10. Date of hospitalisation: / /

A11. Does the patient require oxygen?

A12. Does the patient **CURRENTLY** require ventilation or ECMO?
Invasive mechanical ventilation or extra-corporeal membrane oxygenation

Does the patient have any CURRENT comorbidities or other medical problems?

A13.1 Diabetes

A13.2 Heart disease

A13.3 Chronic lung disease

A13.4 Tuberculosis

A13.5 HIV

A13.6 Severe liver disease

A13.7 Severe kidney impairment (eGFR<30 or on dialysis)

A13.8 Known long QT syndrome

A13.9 Current treatment with macrolide antibiotics which are to continue
Macrolide antibiotics include clarithromycin, azithromycin and erythromycin

Are the following treatments UNSUITABLE for the patient?
If you answer Yes it means you think this participant should NOT receive this drug.

A13.10 Previous adverse reaction to blood or blood product transfusion

A14.1 Lopinavir-Ritonavir

A14.2 Corticosteroids

A14.3 Hydroxychloroquine

Are the following treatments available?

A14.4 Azithromycin

A14B.1 Convalescent plasma

A15.1 Lopinavir-Ritonavir

A15.2 Corticosteroids

A15.3 Hydroxychloroquine

Current medication

A15.4 Azithromycin

Please sign off this form once complete

A15B.1 Convalescent plasma

A16 Is the patient currently prescribed remdesivir?

Surname:

Forename:

Professional email:

Home

Continue

Cancel

Follow-up form

The Follow-up form (shown on the next page) collected information on study treatment adherence (including both the randomized allocation and use of other study treatments), vital status (including date and provisional cause of death if available), hospitalisation status (including date of discharge), respiratory support received during the hospitalisation, occurrence of any major cardiac arrhythmias and renal replacement therapy received.

The following modifications were made to the Follow-up form during the trial:

Follow-up form version	**Date of release**	**Modifications from previous version**
1.0	30-Mar-20	Initial version
2.0	09-Apr-20	Information on other treatments used during admission: • Azithromycin, IL-6 receptor antagonist Fact and result of SARS-CoV-2 PCR test
3.0	09-Apr-20	Update to functionality; no changes to questions
4.0	23-Apr-20	Duration of treatments added
5.0	12-May-20	Capture of major cardiac arrhythmias added
6.0	28-May-20	Updates to wording of questions. Information on other treatments used during admission: • Remdesivir, convalescent plasma

Dexamethasone for COVID-19

Follow-up

Date of randomisation

Patient's date of birth

yyyy-mm-dd

1. Which of following treatment(s) did the patient definitely receive as part of their hospital admission after randomisation? *

(NB Include RECOVERY study-allocated drug, only if given, PLUS any of the other treatments if given as standard hospital care)

- [ ] No additional treatment
- [ ] Lopinavir-ritonavir
- [ ] Corticosteroid (dexamethasone, prednisolone or hydrocortisone)
- [ ] Hydroxychloroquine
- [ ] Azithromycin or other macrolide (eg, clarithromycin, erythromycin)
- [ ] Tocilizumab or sarilumab
- [ ] Remdesivir

The following questions only appear if the treatments have been allocated at randomisation

Please select number of days the patient received lopinavir-ritonavir

1 2 3 4 5 6 7 8 9 10

Please select number of days the patient received corticosteroid (dexamethasone, prednisolone or hydrocortisone)

1 2 3 4 5 6 7 8 9 10

Please select number of days the patient received hydroxychloroquine

1 2 3 4 5 6 7 8 9 10

Please select number of days the patient received azithromycin

This question and the following question cannot both be zero

0 1 2 3 4 5 6 7 8 9 10

Please select number of days the patient received other macrolides (eg, clarithromycin, erythromycin)

0 1 2 3 4 5 6 7 8 9 10

Please select number of doses of tocilizumab or sarilumab the patient received

1 >1

Please select number of days the patient received remdesivir

1 2 3 4 5 6 7 8 9 10

» Convalescent Plasma

How many convalescent plasma infusions did the patient receive?

This is plasma given as part of trial, not any standard fresh frozen plasma or other blood products that the patient may have been given

0 1 2

Were any infusions stopped early for any reason ie, the patient did not receive the full amount?

Yes No

How many were stopped early?

1 2

» Health Status

2. Was a COVID-19 test done for this patient?

(If multiple tests were done, and the results were positive and negative, please tick Yes – positive result and Yes – negative result)

- [ ] Yes – positive result
- [ ] Yes – negative result
- [ ] Not done

3. What is the patient's vital status? *

- Alive
- Dead

3.1 What is the patient's current hospitalisation status?

Q3.1 is only completed if the patients is alive at Q3

- Inpatient
- Discharged

The patient has been enrolled in the trial for **NaN** days

3.1.1 Date follow-up form completed **Q3.1.1 is only completed if patient is still an inpatient at Q3**

yyyy-mm-dd

3.1.1 What was the date of discharge? **Q3.1.1 is only completed if patient has been discharged at Q3**

yyyy-mm-dd

3.1 What was the date of death? **Q3.1.1 is only completed if patient has died at Q3** *

yyyy-mm-dd

3.2 What was the underlying cause of death? *

This can be obtained from the last entry in part 1 of the death certificate

- ◯ COVID-19
- ◯ Other infection
- ◯ Cardiovascular
- ◯ Other

Please give details

4. Did the patient require any form of assisted ventilation (ie, more than just supplementary oxygen)? *

- ◯ Yes
- ◯ No

Please answer the following questions:

4.1 For how many days did the patient require assisted ventilation? *

4.2 What type of ventilation did the patient receive?

	Yes	No	Unknown
CPAP alone	◯	◯	◯
Non-invasive ventilation (eg, BiPAP)	◯	◯	◯
High-flow nasal oxygen (eg, AIRVO)	◯	◯	◯
Mechanical ventilation (intubation/tracheostomy)	◯	◯	◯

ECMO			

Total number of days the patient received invasive mechanical ventilation (intubation/tracheostomy) (from randomisation until discharge/death/28 days after randomisation)

Complete if invasive mechanical ventilation (intubation/tracheostomy) is Yes

5. Has the participant been documented to have a NEW cardiac arrhythmia at any point since the main randomisation?

- ◯ Yes
- ◯ No
- ◯ Unknown

5.1 Please select all of the following which apply

If Q5 is answered Yes, you must select at least one option here

- ☐ Atrial flutter or atrial fibrillation
- ☐ Supraventricular tachycardia
- ☐ Ventricular tachycardia (including torsades de pointes)
- ☐ Ventricular fibrillation
- ☐ Atrioventricular block requiring intervention (eg, cardiac pacing)

6. Did the patient require use of renal dialysis or haemofiltration?

- ◯ Yes
- ◯ No

7. Please enter UKOSS case ID if known *

Enter the full UKOSS case ID ie, COR_123

Complete only if patient was pregnant at randomisation

(select if you do not know the UKOSS case ID)

- ☐ Not known

Interim analyses: role of the Data Monitoring Committee

The independent Data Monitoring Committee reviews unblinded analyses of the study data and any other information considered relevant at intervals of around 2 weeks. The committee is charged with determining if, in their view, the randomized comparisons in the study provide evidence on mortality that is strong enough (with a range of uncertainty around the results that was narrow enough) to affect national and global treatment strategies. In such a circumstance, the Committee would inform the Steering Committee who would make the results available to the public and amend the trial arms accordingly. Unless that happened, the Steering Committee, investigators, and all others involved in the trial would remain blind to the interim results until 28 days after the last patient had been randomized to a particular intervention arm. Further details about the role and membership of the independent Data Monitoring Committee are provided in the protocol.

The Data Monitoring Committee determined that to consider recommending stopping a treatment early for benefit would require at least a 3 to 3.5 standard error reduction in mortality. The Committee concluded that examinations of the data at every 10% (or even 5%) of the total data would lead to only a marginal increase in the overall type I error rate.

The Data Monitoring Committee met to review interim outcome data on dexamethasone on five occasions prior to being informed by the Steering Committee that recruitment to dexamethasone was to be stopped. With the requirement of a 3.5 standard error overall mortality benefit before a recommendation to stop would be made, this means that the alpha ‘spent’ at these interim analyses was only of the order of about 0.06% (hence the alpha preserved to claim significance at the final analysis was 4.94%).

Supplementary Tables

Table S1: Baseline characteristics of patients considered unsuitable for randomization to dexamethasone compared with patients randomized to dexamethasone versus usual care.*

Characteristic	Randomized (N=6425)	Considered unsuitable (N=1707)
Age		
Mean -- yr	66.1±15.7	67.2±14.9
Distribution -- no. (%)		
<70 yr	3646 (57)	920 (54)
≥70 to 79 yr	1328 (21)	416 (24)
≥80 yr	1451 (23)	371 (22)
Sex -- no. (%)		
Male	4087 (64)	1053 (62)
Female	2338 (36)	654 (38)
Race -- no. (%) †		
White	4689 (73)	1326 (78)
Black, Asian or Minority Ethnic group	1147 (18)	273 (16)
Unknown	589 (9)	108 (6)
Median no. of days since symptom onset (IQR)	9 (5-13)	8 (4-12)
Median no. of days since hospitalization (IQR)	2 (1-5)	2 (1-5)
Respiratory support received -- no. (%)		
No oxygen	1535 (24)	490 (29)
Oxygen only	3883 (60)	1058 (62)
Invasive mechanical ventilation	1007 (16)	159 (9)
Previous coexisting disease -- no. (%)		
Any of the listed conditions	3591 (56)	1310 (77)
Diabetes	1546 (24)	791 (46)
Heart disease	1757 (27)	531 (31)
Chronic lung disease	1346 (21)	511 (30)
Tuberculosis	25 (<1)	6 (<1)
HIV infection	32 (<1)	16 (1)
Severe liver disease ‡	119 (2)	27 (2)
Severe kidney impairment §	524 (8)	202 (12)
SARS-Cov-2 test result -- no. (%)		
Positive	5744 (89)	1505 (88)
Negative	650 (10)	193 (11)
Unknown	31 (<1)	9 (1)

* Plus–minus values are means ±SD. HIV denotes human immunodeficiency virus, IQR interquartile range, and SARS-CoV-2 severe acute respiratory syndrome coronavirus 2.

† Race (ethnic group) is reported as it was recorded in the patient's electronic health record.

‡ Severe liver disease was defined as requiring ongoing specialist care

§ Severe kidney impairment was defined as an estimated glomerular filtration rate of less than 30 ml per minute per 1.73 m^2

Table S2: Treatments given, by randomized allocation

	Dexamethasone (N=2104)	Usual Care (N=4321)
Compliance data available	2095	4306
Corticosteroid received -- no. (%)	1996 (95)	347 (8)
Other treatments received -- no. (%)		
Lopinavir-ritonavir	1 (<1)	4 (<1)
Hydroxychloroquine	16 (1)	22 (1)
Azithromycin or other macrolides	507 (24)	1110 (26)
Tocilizumab or sarilumab	45 (2)	132 (3)
Remdesivir	2 (<1)	0 (0)

Percentages are of those with a completed follow-up form. Remdesivir only became available for use in the UK under the Medicines & Healthcare Products Regulatory Agency Emergency Access to Medicines Scheme on 26 May 2020. In addition to the 2 patients recorded on the follow-up as having taken remdesivir, 1 patient allocated dexamethasone and 2 patients allocated usual care were recorded as having been on remdesivir when they were randomized.

Of those allocated dexamethasone who received at least one dose, 76% received all (or nearly all) of their scheduled doses during their hospital stay (missing at most 1 dose) while 89% received at least half of their scheduled doses. The median number of days it was taken was 7 days (IQR 3-10 days).

Table S3: Impact of adjusting for the 1.1-year age imbalance between randomized arms on the estimated effect of allocation to dexamethasone on 28-day mortality, both in all randomized patients and in subgroups defined by respiratory support received at randomization

	no./total no. of patients (%)		Rate ratio (95% CI)	
Subgroup	**Dexamethasone (N=2104)**	**Usual Care (N=4321)**	**Age-adjusted Cox regression***	**One-step estimate†**
No oxygen received	89/501 (17.8)	145/1034 (14.0)	1.19 (0.92-1.55)	1.30 (0.99-1.72)
Oxygen only	298/1279 (23.3)	682/2604 (26.2)	0.82 (0.72-0.94)	0.86 (0.75-0.99)
Invasive mechanical ventilation	95/324 (29.3)	283/683 (41.4)	0.64 (0.51-0.81)	0.67 (0.54-0.84)
All participants	**482/2104 (22.9)**	**1110/4321 (25.7)**	**0.83 (0.75-0.93)**	**0.87 (0.78-0.97)**

* Main analysis shown in Figures 2 and 3, in which the 28-day age-adjusted (ie, conditional) mortality rate ratio is estimated by the hazard ratio from a Cox regression analysis adjusted for age in three categories (<70 years, 70-79 years, and 80 years or older). There was a clear trend towards greater benefit among patients requiring higher levels of respiratory support (chi-squared trend statistic = 11.6).

† Original pre-specified analysis without adjustment for the 1.1-year age-imbalance between the randomized groups. With this method the 'one-step' method is used to estimate the average unadjusted (ie, marginal) mortality rate ratio from the log-rank 'observed minus expected' statistic (O –E) and its variance (V), through the formula exp([O – E] ÷ V). Its 95% CI is then given by exp([O – E] ÷ V ± 1.96 ÷ √V). There was a clear trend towards greater benefit among patients requiring higher levels of respiratory support (chi-squared trend statistic = 13.1).

Table S4: Baseline characteristics by randomized allocation, separately among those not receiving oxygen at randomization, those receiving oxygen only, and those on invasive mechanical ventilation

	No Receipt of Oxygen		Oxygen Only		Invasive Mechanical Ventilation	
	Dexamethasone (N=501)	Usual Care (N=1034)	Dexamethasone (N=1279)	Usual Care (N=2604)	Dexamethasone (N=324)	Usual Care (N=683)
Age						
Mean -- yr	71.1±16.3	68.5±18.0	67.2±15.2	66.4±15.3	58.8±11.3	59.2±11.5
Distribution -- no. (%)						
<70 yr	197 (39)	462 (45)	675 (53)	1474 (57)	269 (83)	569 (83)
≥70 to 79 yr	114 (23)	224 (22)	306 (24)	531 (20)	49 (15)	104 (15)
≥80 yr	190 (38)	348 (34)	298 (23)	599 (23)	6 (2)	10 (1)
Sex -- no. (%)						
Male	286 (57)	605 (59)	819 (64)	1643 (63)	233 (72)	501 (73)
Female	215 (43)	429 (41)	460 (36)	961 (37)	91 (28)	182 (27)
Race -- no. (%) †						
White	410 (82)	811 (78)	957 (75)	1937 (74)	183 (56)	391 (57)
Black, Asian or Minority Ethnic group	48 (10)	143 (14)	215 (17)	447 (17)	101 (31)	193 (28)
Unknown	43 (9)	80 (8)	107 (8)	220 (8)	40 (12)	99 (14)
Median no. of days since symptom onset (IQR)	6 (3-10)	7 (3-10)	8 (5-13)	9 (5-12)	13 (9-18)	13 (8-18)
Median no. of days since hospitalization (IQR)	2 (1-6)	2 (1-5)	2 (1-4)	2 (1-4)	5 (3-10)	5 (3-9)
Previous coexisting disease -- no. (%)						
Any of the listed conditions	313 (62)	598 (58)	702 (55)	1473 (57)	159 (49)	346 (51)
Diabetes	119 (24)	223 (22)	320 (25)	630 (24)	82 (25)	172 (25)
Heart disease	180 (36)	339 (33)	357 (28)	717 (28)	49 (15)	115 (17)
Chronic lung disease	121 (24)	230 (22)	259 (20)	624 (24)	35 (11)	77 (11)
Tuberculosis	2 (<1)	6 (1)	1 (<1)	10 (<1)	3 (1)	3 (<1)
HIV infection	2 (<1)	3 (<1)	9 (1)	12 (<1)	1 (<1)	5 (1)
Severe liver disease ‡	13 (3)	19 (2)	20 (2)	52 (2)	4 (1)	11 (2)
Severe kidney impairment §	28 (6)	91 (9)	85 (7)	168 (6)	53 (16)	99 (14)
SARS-Cov-2 test result -- no. (%)						
Positive	427 (85)	913 (88)	1130 (88)	2303 (88)	308 (95)	663 (97)
Negative	70 (14)	120 (12)	141 (11)	288 (11)	14 (4)	17 (2)
Unknown	4 (1)	1 (<1)	8 (1)	13 (<1)	2 (1)	3 (<1)

* Plus–minus values are means ±SD. HIV denotes human immunodeficiency virus, IQR interquartile range, and SARS-CoV-2 severe acute respiratory syndrome coronavirus 2.

† Race (ethnic group) is reported as it was recorded in the patient's electronic health record.

‡ Severe liver disease was defined as requiring ongoing specialist care

§ Severe kidney impairment was defined as an estimated glomerular filtration rate of less than 30 ml per minute per 1.73 m^2

Table S5: Effect of allocation to dexamethasone on cause-specific 28-day mortality.*

Cause of death	no./total no. of patients (%)		Rate Ratio (95% CI)*
	Dexamethasone (N=2104)	Usual Care (N=4321)	
COVID-19	438 (20.8)	1027 (23.8)	0.82 (0.73-0.92)
Other infection	6 (0.3)	9 (0.2)	1.26 (0.45-3.56)
Cardiac	2 (0.1)	7 (0.2)	0.55 (0.11-2.64)
Stroke	4 (0.2)	5 (0.1)	1.53 (0.41-5.71)
Other vascular	1 (0.0)	3 (0.1)	0.64 (0.07-6.16)
Cancer	11 (0.5)	15 (0.3)	1.39 (0.64-3.03)
Other medical	18 (0.9)	43 (1.0)	0.80 (0.46-1.38)
External	2 (0.1)	0 (0.0)	-
Unknown cause	0 (0.0)	1 (0.0)	-
Total: 28-day mortality	482 (22.9)	1110 (25.7)	0.83 (0.75-0.93)

* Rate ratios have been adjusted for age.

Table S6: Effect of allocation to dexamethasone on new major cardiac arrhythmia.

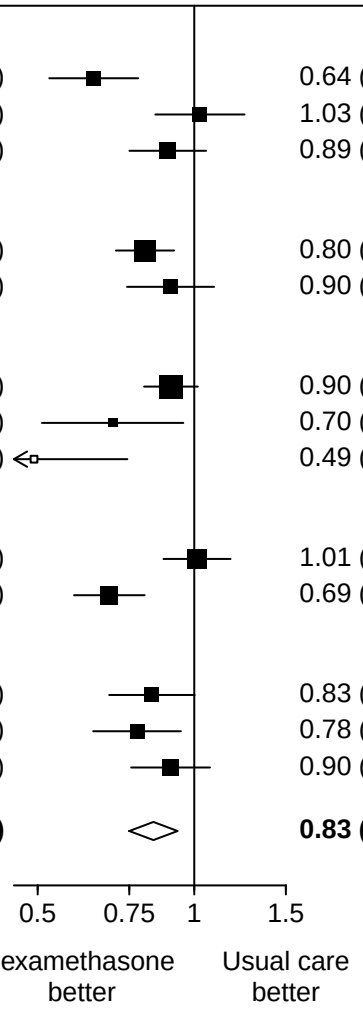
	no./total no. of patients (%)	
	Dexamethasone (N=2104)	**Usual Care (N=4321)**
Number with follow-up form*	973	1940
Atrial flutter or atrial fibrillation	42 (4.3)	94 (4.8)
Other supraventricular tachycardia	3 (0.3)	24 (1.2)
Subtotal: Supraventricular tachycardia	45 (4.6)	110 (5.7)
Ventricular tachycardia	8 (0.8)	10 (0.5)
Ventricular fibrillation	0 (0)	3 (0.2)
Subtotal: Ventricular tachycardia or fibrillation	8 (0.8)	12 (0.6)
Atrioventricular block requiring intervention	1 (0.1)	1 (<0.1)
Total: Any major cardiac arrhythmia	52 (5.3)	122 (6.3)

* Information on new cardiac arrhythmias was only collected on follow-up forms from 12 May 2020 onwards; percentages are of those with such a form completed.

Supplementary Figures

Figure S1: Effect of allocation to dexamethasone on 28−day mortality by other pre−specified baseline characteristics

Characteristic	Dexamethasone	Usual care	RR (95% CI)	Het./ trend
Age				
<70	129/1141 (11.3%)	429/2505 (17.1%)	0.64 (0.53−0.78)	χ^2_1=5.2
≥70 <80	155/469 (33.0%)	271/859 (31.5%)	1.03 (0.84−1.25)	
≥80	198/494 (40.1%)	410/957 (42.8%)	0.89 (0.75−1.05)	
Sex				
Men	331/1338 (24.7%)	782/2749 (28.4%)	0.80 (0.71−0.91)	χ^2_1=0.9
Women	151/766 (19.7%)	328/1572 (20.9%)	0.90 (0.74−1.09)	
Race				
White	401/1550 (25.9%)	849/3139 (27.0%)	0.90 (0.80−1.02)	χ^2_1=2.3
Black, Asian, or minority ethnic group	52/364 (14.3%)	160/783 (20.4%)	0.70 (0.51−0.95)	
Unknown	29/190 (15.3%)	101/399 (25.3%)	0.49 (0.33−0.74)	
Days since symptom onset				
≤7	269/916 (29.4%)	500/1801 (27.8%)	1.01 (0.87−1.17)	χ^2_1=12.4
>7	212/1184 (17.9%)	604/2507 (24.1%)	0.69 (0.59−0.80)	
Baseline risk				
<30%	150/1268 (11.8%)	378/2683 (14.1%)	0.83 (0.69−1.00)	χ^2_1=0.4
≥30% <45%	147/464 (31.7%)	334/878 (38.0%)	0.78 (0.64−0.94)	
≥45%	185/372 (49.7%)	398/760 (52.4%)	0.90 (0.76−1.07)	
All participants	**482/2104 (22.9%)**	**1110/4321 (25.7%)**	**0.83 (0.75−0.93) p<0.001**	



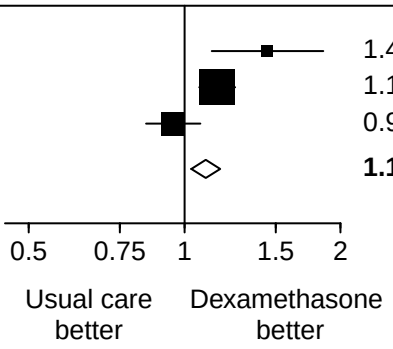
RR=age−adjusted (or age−specific) rate ratio (with the exception of RR estimates by baseline−predicted risk, which are not adjusted for age). CI=confidence interval. Subgroup−specific RR estimates are represented by squares (with areas of the squares proportional to the amount of statistical information) and the lines through them correspond to the 95% confidence intervals. For each of the four subgroups shown, the RRs and CIs are estimated from a regression model that includes a relevant interaction term enabling the effect of allocation to dexamethasone on mortality to be estimated separately at each level of the subgroup. Baseline−predicted risk is calculated as exp(a)/(1 + exp(a)), where a = −1.23 − 2.85 (if age <50) − 2.03 (if age 50−59) − 1.21 (if age 60−69) − 0.51 (if age 70−79) + 0.42 (if male) − 0.34 (if >7 days since symptom onset) + 0.86 (if on oxygen only) + 2.18 (if on invasive mechanical ventilation) − 0.01 (if history of diabetes) + 0.22 (if history of heart disease) + 0.21 (if history of chronic lung disease) + 0.50 (if history of kidney disease). The chi−squared heterogeneity or trend statistics are shown; for race, the statistic corresponds to a test of the White vs the Black, Asian and minority ethnic subgroups.

Figure S2: Effect of allocation to dexamethasone on: a) discharge from hospital alive within 28 days; and b) invasive mechanical ventilation or death, by level of respiratory support received at randomization

a) Discharge from hospital alive within 28 days

Respiratory support at randomization	Dexamethasone	Usual care	RR (95% CI)
Invasive mechanical ventilation	104/324 (32.1%)	157/683 (23.0%)	1.45 (1.13−1.85)
Oxygen only	925/1279 (72.3%)	1760/2604 (67.6%)	1.16 (1.07−1.25)
No oxygen received	387/501 (77.2%)	831/1034 (80.4%)	0.95 (0.84−1.07)
All participants	**1416/2104 (67.3%)**	**2748/4321 (63.6%)**	**1.10 (1.03−1.17)**

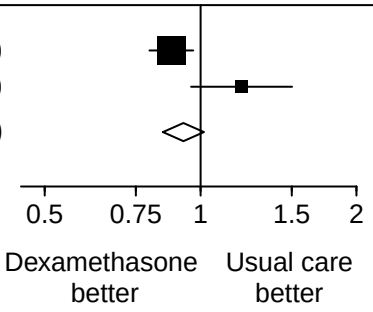
Trend across three categories: χ^2_1=11.7



b) Invasive mechanical ventilation or death (among those not on invasive mechanical ventilation at randomization)

Respiratory support at randomization	Dexamethasone	Usual care	RR (95% CI)
Oxygen only	365/1279 (28.5%)	844/2604 (32.4%)	0.88 (0.80−0.97)
No oxygen received	97/501 (19.4%)	159/1034 (15.4%)	1.20 (0.96−1.50)
Subtotal	**462/1780 (26.0%)**	**1003/3638 (27.6%)**	**0.93 (0.85−1.01)**

Trend across two categories: χ^2_1=6.3



RR=age−adjusted rate ratio for panel a and age−adjusted risk ratio for panel b. CI=confidence interval. Subgroup−specific RR estimates are represented by squares (with areas of the squares proportional to the amount of statistical information) and the lines through them correspond to the 95% confidence intervals. For each analysis, the RRs and CIs are estimated from a regression model that includes a relevant interaction term enabling the effect of allocation to dexamethasone to be estimated separately for each level of the subgroup. For both outcomes, there was a clear trend towards greater proportional benefit among those requiring higher levels of respiratory support. The 'oxygen only' group includes non−invasive ventilation.

Figure S3: Discharge from hospital in all patients (panel a) and separately according to level of respiratory support received at randomization (panels b−d)

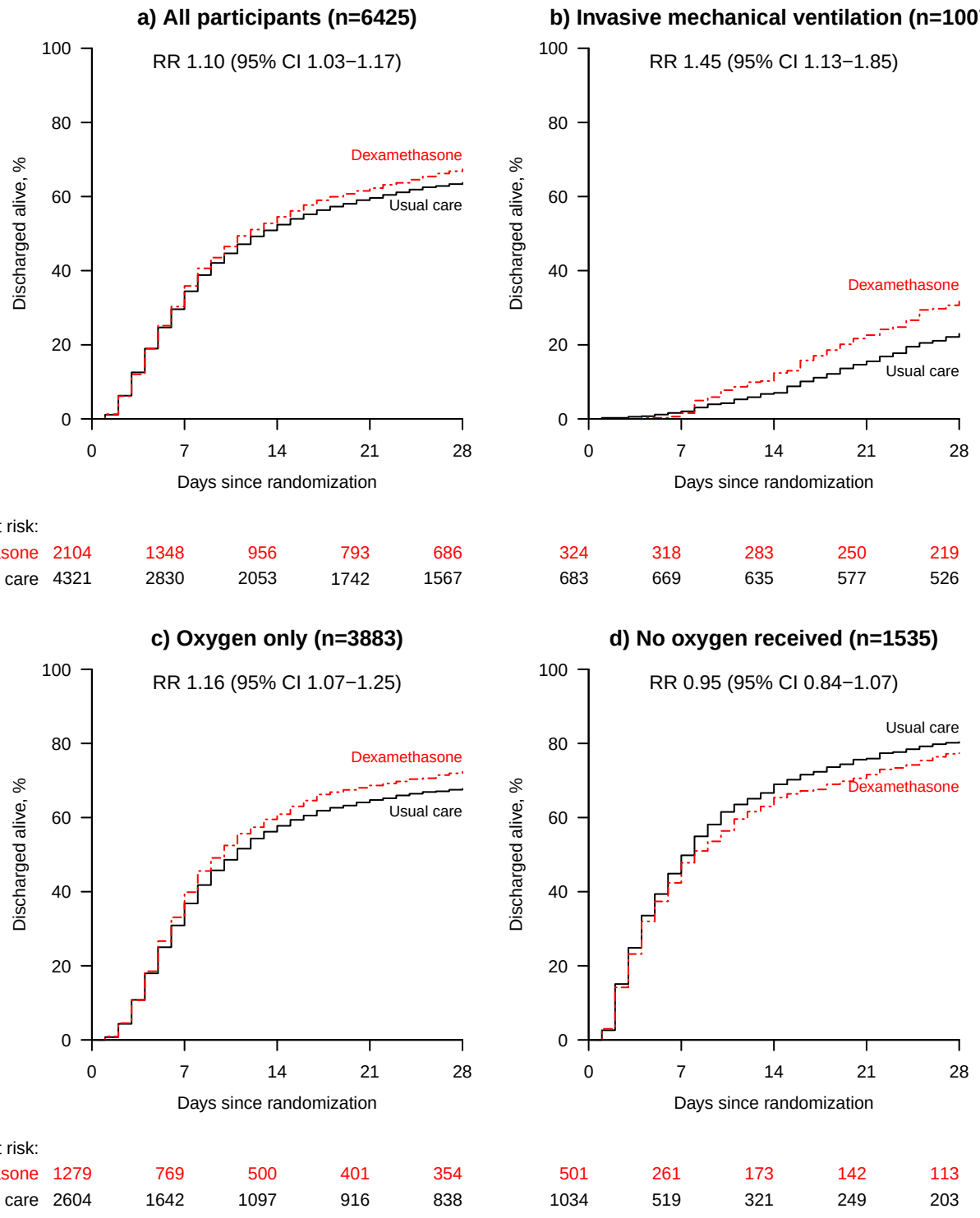
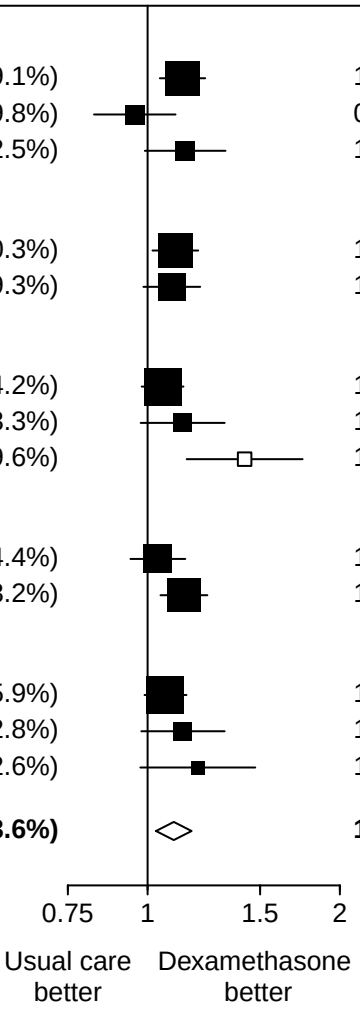


Figure S4: Effect of allocation to dexamethasone on discharge from hospital alive within 28 days, by other pre−specified baseline characteristics

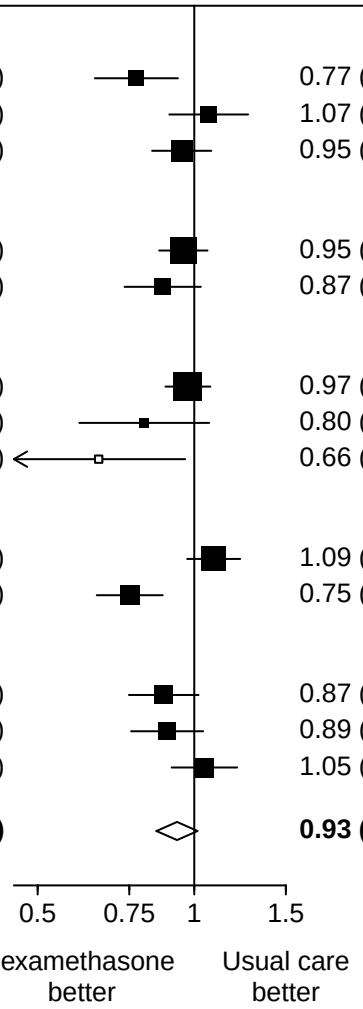
Characteristic	Dexamethasone	Usual care	RR (95% CI)	Het./ trend
Age				
<70	858/1141 (75.2%)	1732/2505 (69.1%)	1.13 (1.04−1.23)	χ^2_1=0.2
≥70 <80	273/469 (58.2%)	514/859 (59.8%)	0.95 (0.82−1.11)	
≥80	285/494 (57.7%)	502/957 (52.5%)	1.15 (0.99−1.32)	
Sex				
Men	862/1338 (64.4%)	1659/2749 (60.3%)	1.11 (1.02−1.20)	χ^2_1=0.0
Women	554/766 (72.3%)	1089/1572 (69.3%)	1.09 (0.98−1.21)	
Race				
White	1023/1550 (66.0%)	2014/3139 (64.2%)	1.06 (0.98−1.14)	χ^2_1=0.7
Black, Asian, or minority ethnic group	253/364 (69.5%)	496/783 (63.3%)	1.13 (0.98−1.32)	
Unknown	140/190 (73.7%)	238/399 (59.6%)	1.42 (1.15−1.75)	
Days since symptom onset				
≤7	597/916 (65.2%)	1160/1801 (64.4%)	1.04 (0.94−1.15)	χ^2_1=2.0
>7	816/1184 (68.9%)	1584/2507 (63.2%)	1.14 (1.05−1.24)	
Baseline risk				
<30%	1007/1268 (79.4%)	2036/2683 (75.9%)	1.07 (0.99−1.15)	χ^2_1=1.4
≥30% <45%	269/464 (58.0%)	464/878 (52.8%)	1.14 (0.98−1.32)	
≥45%	140/372 (37.6%)	248/760 (32.6%)	1.20 (0.97−1.47)	
All participants	**1416/2104 (67.3%)**	**2748/4321 (63.6%)**	**1.10 (1.03−1.17)**	



RR=age−adjusted (or age−specific) rate ratio (with the exception of RR estimates by baseline−predicted risk, which are not adjusted for age). CI=confidence interval. Subgroup−specific RR estimates are represented by squares (with areas of the squares proportional to the amount of statistical information) and the lines through them correspond to the 95% confidence intervals. For each of the four subgroups shown, the RRs and CIs are estimated from a regression model that includes a relevant interaction term enabling the effect of allocation to dexamethasone to be estimated separately at each level of the subgroup. Baseline−predicted risk is calculated as exp(a)/(1 + exp(a)), where a = −1.23 − 2.85 (if age <50) − 2.03 (if age 50−59) − 1.21 (if age 60−69) − 0.51 (if age 70−79) + 0.42 (if male) − 0.34 (if >7 days since symptom onset) + 0.86 (if on oxygen only) + 2.18 (if on invasive mechanical ventilation) − 0.01 (if history of diabetes) + 0.22 (if history of heart disease) + 0.21 (if history of chronic lung disease) + 0.50 (if history of kidney disease). The chi−squared heterogeneity or trend statistics are shown; for race, the statistic corresponds to a test of the White vs the Black, Asian and minority ethnic subgroups.

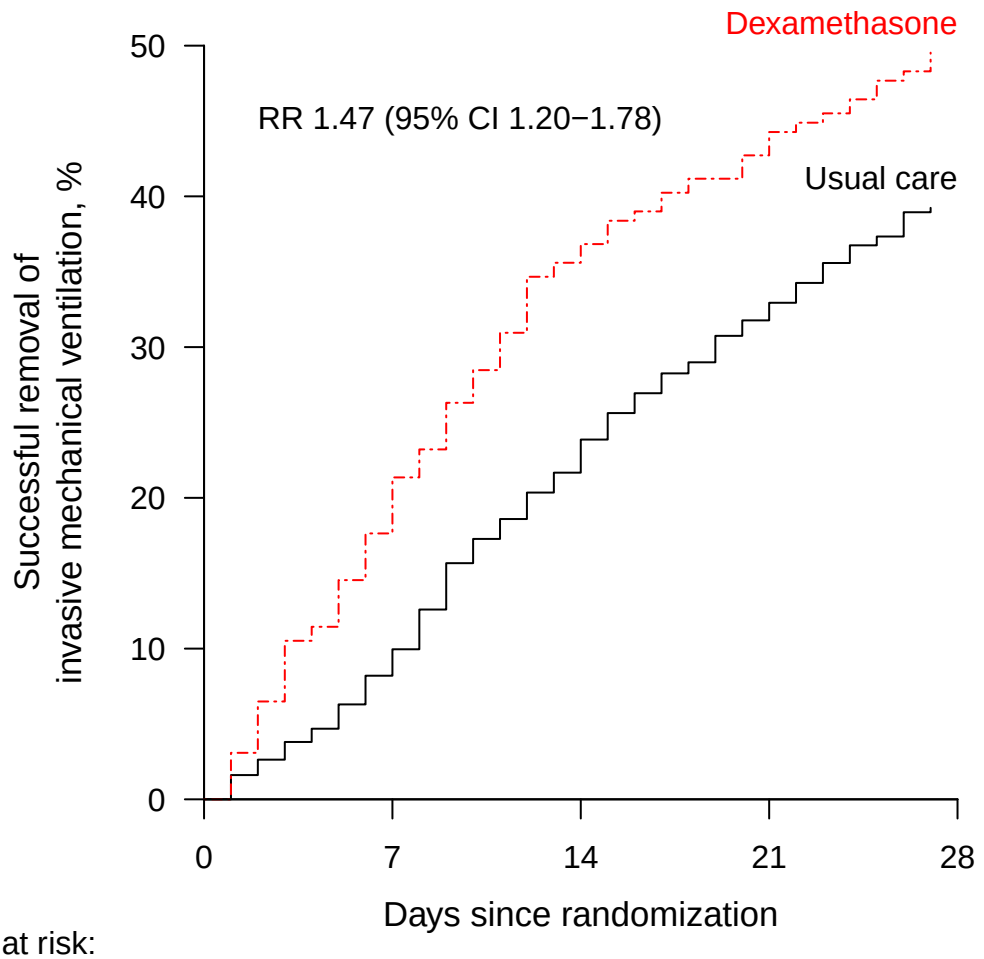
Figure S5: Effect of allocation to dexamethasone on invasive mechanical ventilation or death, by other pre−specified baseline characteristics

Characteristic	Dexamethasone	Usual care	RR (95% CI)	Het./ trend
Age				
<70	129/872 (14.8%)	370/1936 (19.1%)	0.77 (0.64−0.93)	χ^2_1=2.0
≥70 <80	137/420 (32.6%)	231/755 (30.6%)	1.07 (0.90−1.27)	
≥80	196/488 (40.2%)	402/947 (42.4%)	0.95 (0.83−1.08)	
Sex				
Men	320/1105 (29.0%)	671/2248 (29.8%)	0.95 (0.86−1.06)	χ^2_1=0.8
Women	142/675 (21.0%)	332/1390 (23.9%)	0.87 (0.73−1.03)	
Race				
White	387/1367 (28.3%)	784/2748 (28.5%)	0.97 (0.88−1.07)	χ^2_1=1.5
Black, Asian, or minority ethnic group	48/263 (18.3%)	143/590 (24.2%)	0.80 (0.60−1.07)	
Unknown	27/150 (18.0%)	76/300 (25.3%)	0.66 (0.45−0.96)	
Days since symptom onset				
≤7	279/853 (32.7%)	483/1651 (29.3%)	1.09 (0.97−1.23)	χ^2_1=15.1
>7	182/924 (19.7%)	513/1976 (26.0%)	0.75 (0.65−0.87)	
Baseline risk				
<30%	189/1134 (16.7%)	459/2406 (19.1%)	0.87 (0.75−1.02)	χ^2_1=2.9
≥30% <45%	141/402 (35.1%)	303/766 (39.6%)	0.89 (0.76−1.04)	
≥45%	132/244 (54.1%)	241/466 (51.7%)	1.05 (0.90−1.21)	
All participants	**462/1780 (26.0%)**	**1003/3638 (27.6%)**	**0.93 (0.85−1.01)**	



RR=age−adjusted (or age−specific) risk ratio (with the exception of RR estimates by baseline−predicted risk, which are not adjusted for age). CI=confidence interval. Subgroup−specific RR estimates are represented by squares (with areas of the squares proportional to the amount of statistical information) and the lines through them correspond to the 95% confidence intervals. For each of the four subgroups shown, the RRs and CIs are estimated from a regression model that includes a relevant interaction term enabling the effect of allocation to dexamethasone to be estimated separately at each level of the subgroup. Baseline−predicted risk is calculated as exp(a)/(1 + exp(a)), where a = −1.23 − 2.85 (if age <50) − 2.03 (if age 50−59) − 1.21 (if age 60−69) − 0.51 (if age 70−79) + 0.42 (if male) − 0.34 (if >7 days since symptom onset) + 0.86 (if on oxygen only) + 2.18 (if on invasive mechanical ventilation) − 0.01 (if history of diabetes) + 0.22 (if history of heart disease) + 0.21 (if history of chronic lung disease) + 0.50 (if history of kidney disease). The chi−squared heterogeneity or trend statistics are shown; for race, the statistic corresponds to a test of the White vs the Black, Asian and minority ethnic subgroups.

Figure S6: Successful removal of invasive mechanical ventilation (among those on invasive mechanical ventilation at randomization)



Number at risk:					
Dexamethasone	324	254	204	180	163
Usual care	683	615	520	458	415