Supplementary Material for the 2025 Clinical Practice Guideline Update by the Infectious Diseases Society of America on the Treatment and Management of COVID-19: Baricitinib vs. Tocilizumab

Table of Contents

METHODS

Panel formation and conflicts of interest

The chair and vice chair of the guideline panel were selected by the leadership of IDSA. Twenty-six additional panelists comprised the full panel. The panel included clinicians with expertise in infectious diseases, pediatric infectious diseases, critical care medicine, pulmonology, maternal fetal medicine, and pharmacology, as well as biostatistics. Guideline methodologists oversaw all methodological aspects of the guideline development, including the identification and summarization of scientific evidence for each clinical question. IDSA staff oversaw all administrative and logistic issues related to the guideline panel.

All members of the expert panel complied with the IDSA policy on conflict of interest (COI), which requires disclosure of any financial, intellectual, or other interest that might be construed as constituting an actual, potential, or apparent conflict. Evaluation of such relationships as potential conflicts of interest was determined by a review process which included assessment by the Standards and Practice Guidelines Subcommittee (SPGS) Chair, and if necessary, the Conflict of Interests Ethics Committee. This assessment of disclosed relationships for possible COI was based on the relative weight of the financial relationship (i.e., monetary amount) and the relevance of the relationship (i.e., the degree to which an independent observer might reasonably interpret an association as related to the topic or recommendation of consideration). The reader of these guidelines should be mindful of this when the list of disclosures is reviewed. See the Notes section at the end of the guideline for the disclosures reported to IDSA.

Practice recommendations

Clinical Practice Guidelines are statements that include recommendations intended to optimize patient care by assisting practitioners and patients in making shared decisions about appropriate health care for specific clinical circumstances. These are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options [IOM 2011]. The "IDSA Handbook on Clinical Practice Guideline Development" provides more detailed information on the processes followed throughout the development of this guideline [IDSA CPG Handbook].

Review and approval process

Feedback was obtained from two external individual peer expert reviewers as well as the endorsing organizations. The IDSA Standards and Practice Guidelines Subcommittee (SPGS) and Board of Directors reviewed and approved the guideline prior to publication.

Process for updating

IDSA guidelines are regularly reviewed for currency. The need for updates to the guideline is determined by a scan of current literature and the likelihood that any new data would impact the recommendations. Any changes to the guideline will be submitted for review and approval to the appropriate Committees and Board of IDSA.

Clinical questions

Each clinical question was formatted according to the PICO style: Patient/Population (P), Intervention/Indicator (I), Comparator/Control (C), Outcome (O). For each PICO question, outcomes of interest were identified a priori and rated for their relative importance for decision-making.

Literature search

A literature search was conducted in Ovid Medline, Embase, and Cochrane Library in February 2025. Searches were limited to studies published in English.

PubMed search strategy (similar strategies applied for Embase and Cochrane Library):
("COVID-19"[Mesh] OR "COVID-19 Drug Treatment"[Mesh] OR "SARS-CoV-2"[Mesh] OR "2019 novel"[tiab] OR "2019-ncov"[tiab] OR 2019ncov[tiab] OR "coronavirus disease 19"[tiab] OR covid19[tiab] OR covid2019[tiab] OR "covid 2019"[tiab] OR "covid-19"[tiab] OR "hcov-19"[tiab] OR hcov19[tiab] OR "n-cov"[tiab] OR "ncov-2019"[tiab] OR ncov[tiab] OR ncov2019[tiab] OR "novel betacoronavirus"[tiab] OR "Novel Coronavirus"[tiab] OR "novel CoV"[tiab] OR "sars coronavirus 2"[tiab] OR "sars-cov19"[tiab] OR "sars-cov-19"[tiab] OR sarscov19[tiab] OR "sarscov2"[tiab] OR "sarscov-2"[tiab] OR "sars-cov2"[tiab] OR "sars-cov-2"[tiab] OR "severe acute respiratory syndrome coronavirus 2"[tiab]) AND

(("tocilizumab"[Supplementary Concept] OR Actemra[tiab] OR atlizumab[tiab] OR BAT1806[tiab] OR "BAT-1806"[tiab] OR "monoclonal antibodies, MRA"[tiab] OR "monoclonal antibody, MRA"[tiab] OR "MRA monoclonal antibodies"[tiab] OR "MRA monoclonal antibody"[tiab] OR MSB11456[tiab] OR "MSB-11456"[tiab] OR "R-1569"[tiab] OR "RG-1569"[tiab] OR "RHPM-1"[tiab] OR "RO-4877533"[tiab] OR roactemra[tiab] OR tocilizumab[tiab]) AND ("baricitinib"[Supplementary Concept] OR baricitinib[tiab] OR INCB028050[tiab] OR "INCB-028050"[tiab] OR "INCB-28050"[tiab] OR LY3009104[tiab] OR "LY-3009104"[tiab] OR olumiant[tiab]))

Study selection

Inclusion and exclusion criteria were pre-defined. The eligibility criteria below were used.

Inclusion criteria:

- *Patient population*- Patients with severe or critical COVID-19
- *Intervention*- Baricitinib
- *Comparator*- Tocilizumab
- *Outcomes*- Mortality, progression to mechanical ventilation, progression to ECMO, serious adverse events
- *Study design***-** RCTs and nonrandomized studies

Exclusion criteria:

- *Patient population*- Patients without severe or critical COVID-19
- *Intervention*- N/A
- *Comparator*- N/A
- *Study design***-** Review articles, case reports

Data extraction and analysis

Guideline methodologists, with panelist assistance, extracted the data for each pre-determined patient-important outcome. If a relevant publication was missing raw data for an outcome prioritized by the panel, an attempt was made to contact the author(s) for the missing data.

Evidence to decision

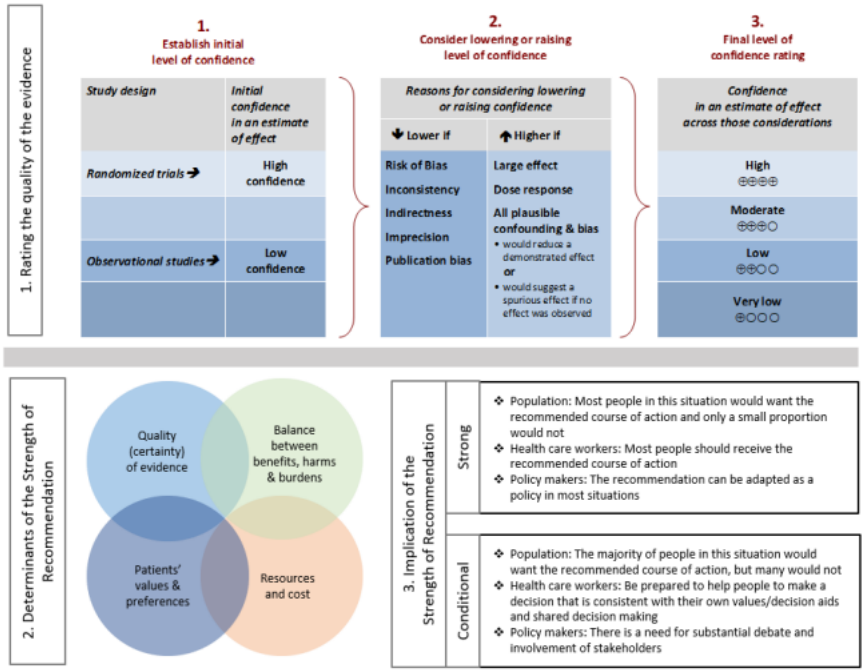
Guideline methodologists prepared the evidence summaries for each question and assessed the risk of bias and the certainty of evidence. Risk of bias was assessed by using the Cochrane Risk of Bias 2.0 tool for RCTs and the ROBINS-I V2 for non-randomized studies [ROBINS-I V2, Sterne 2019]. The certainty of evidence was determined first for each critical and important outcome and then for each recommendation using the GRADE approach for rating the confidence in the evidence [Guyatt 2008, GRADE Handbook/Schunemann]. Evidence profiles were developed using the GRADEpro Guideline Development Tool [Guyatt 2008] and reviewed by panel members.

The Evidence to Decision framework [GRADEpro] was used to translate the evidence summaries into a practice recommendation. All recommendations are labeled as either “strong” or “conditional” according to the GRADE approach [IDSA CPG Handbook]. The words “we recommend” indicate strong recommendations and “we suggest” indicate conditional recommendations. Supplementary Figure 1 provides the suggested interpretation of strong and conditional recommendations for patients, clinicians, and healthcare policymakers. For recommendations where the comparator treatment or tests are not formally stated, the comparison of interest is implicitly referred to as “not using the intervention” (either not using a specific treatment or a diagnostic test).

All members of the panel participated in the preparation of the draft guideline and approved the recommendation.

TABLES AND FIGURES

Supplementary Figure 1. Approach and implications to rating the quality of evidence and strength of recommendations using GRADE methodology (unrestricted use of figure granted by the U.S. GRADE Network)



Supplementary Table 1. Characteristics of included studies

Author Year	Country/ Hospital	Study design	N (Baricitinib/Tocilizumab); % female	Age mean (SD)/ Median (IQR)	Severity of disease	Baricitinib treatment information	Tocilizumab treatment information	Co-interventions	Relevant outcomes	Funding source
Conroy 2024	10 hospitals in USA 1/2021-11/2021	Retrospective cohort	507 (290/217); 44.2% female	Median (IQR) Baricitinib: 61.5 (51-71) Tocilizumab: 62.0 (50-70)	Critically ill adults who were PCR-positive for SARS-CoV-2 and required ICU admission	Median oral dose of 4 mg for a median duration of 9 days	Median dose of 730 mg	Remdesivir, dexamethasone, hydrocortisone, prednisone, methylprednisolone, continuous paralysis, inhaled epoprostenol	28-day in-hospital mortality, Hospitalized on NIV or HF O_2 devices, New mechanical ventilation requirement, Mechanical ventilation pO_2/FiO_2 <150 and vasopressors, dialysis, or ECMO, Adverse events, Lymphopenia, Neutropenia, Secondary infection	Not reported
Karampitsakos 2023	1 hospital in Greece 10/2021-5/2022	RCT	251 (125/126); 41.0% female	Median (IQR) Baricitinib: 73 (61-83) Tocilizumab: 72 (62-83)	Patients >18 years with COVID-19 with a partial pressure of oxygen in the arterial blood (PaO_2)/fraction of inspired oxygen (FiO_2) ratio of <200 at any time during their hospitalization	4 mg/day orally (or 2 mg/day for patients with an estimated glomerular filtration rate of 30 to <60 mL/min/1.73 m^2) once daily for 14 days or until discharge	8 mg/kg for a single dose administered IV over 60 minutes, with potential for a second dose within 48 hours	Dexamethasone, remdesivir, anticoagulants (fondaparinux), antibiotic compounds, vasopressor support	Mortality at day 28; Mechanical ventilation; Adverse events: Lobar consolidation, cardiac event, major bleeding, septic shock, thrombocytosis; Increased CPK 5 times greater than the upper reference value; Increased SGOT/SGPT 3 times greater than the upper reference value	Not reported

Karolyi 2023	1 hospital in Austria 2/2021-12/2021	Retrospective cohort	159 (91/68); 36.5% female	Mean (SD) Baricitinib: 62.2 (16.8) Tocilizumab: 58.2 (14.3)	COVID-19 patients with rapid disease progression (e.g., rapid deterioration from no oxygen to high-flow within 48 h), high oxygen demand on admission or patients with risk factors for progression (age, BMI, medical history) plus elevated C-reactive protein (CRP) plus low-flow oxygen	4 mg (GFR>60 ml/min) or 2 mg (GFR 30–60 ml/min) orally once daily for 14 days	Single dose administered IV based on body weight 90 kg: 800 mg, ≤90 kg: 600 mg, ≤65 kg: 400 mg, ≤40 kg: 8 mg/kg	Oxygen insufflation, dexamethasone, low-molecular-weight-heparin, remdesivir, monoclonal antibodies	In-hospital mortality; Progression to MV; Adverse events: Bacterial superinfection, ALAT elevation >3 ULN, lymphopenia <0.2 G/l, thrombotic event, Herpes reactivation	None
Kojima 2022	1 hospital in Japan 8/2020-9/2021	Retrospective cohort	98 (34/64); 25.5% female	Median (IQR) Baricitinib: 58.5 (53.8-64.3) Tocilizumab: 65.5 (54.3-72.8)	Hospitalized COVID-19 patients with an oxygen requirement criterion of deterioration of ≥5 L/min in the oxygen administration rate	4 mg once daily for 14 days administered orally or via nasogastric tube	Single 8 mg/kg dose administered IV	Steroids, heparin, antivirals, monoclonal antibodies	Death within 28 days; Adverse events: Pneumonia, bacteremia, urinary tract infection, fungal infection	None
Lakatos 2022	1 hospital in Hungary 8/2020-4/2021	Prospective cohort	463 (361/102); 38.4% female	Median (IQR) Baricitinib: 63.1 (40.6-85.6) Tocilizumab: 63.5 (36.1-90.9)	Hospitalized adults with severe COVID-19 and cytokine storm	4 mg orally or via nasogastric tube and once daily for a minimum of 7 days	Single 8 mg/kg dose administered IV	Oxygen support, remdesivir, dexamethasone	All-cause mortality; Requirement of invasive mechanical ventilation; Adverse events: Bacterial infection, deep vein thrombosis, acute	None

									kidney injury, ACS, hemorrhage, arrhythmia	
Patanwala 2025	75 hospitals in USA 1/2020-10/2023	Retrospective cohort	10661 (6229/4432); 39.7% female	Mean (SD) Baricitinib: 60.7 (15) Tocilizumab: 59.1 (15.1)	COVID-19 patients ≥18 years with N3C diagnosis ≤16 days prior, first dose of baricitinib or tocilizumab within 3 days, no prior IL-6/JAK inhibitors, eGFR ≥15 ml/min/1.73m^2, ANC ≥1 x10^9/L, ALC ≥0.2 x10^9/L, Platelets ≥50 x10^9/L, AST/ALT ≤350 IU/L, not pregnant, and site with >10 users of baricitinib or tocilizumab	Not reported	Not reported	Not reported	28-day mortality; Hospital mortality; Adverse events: Hospital-acquired infections	Not reported
Peterson 2023	11 hospitals in USA 6/2021-10/2021	Retrospective cohort	582 (291/291); 50.3% female	Median (IQR) Baricitinib: 56 (44-65) Tocilizumab: 55 (44-65)	Adults ≥18 years with COVID-19 who survived at least 24 hours from hospital admission	Not reported	Not reported	Remdesivir, steroids	In-hospital mortality; Progression to MV or ECMO; Adverse events: Infection, thrombotic events, acute kidney injury, acute liver injury	Wellstar Research Institute
Reid 2023	1 hospital in USA 8/2021-12/2021	Retrospective cohort	176 (115/61); 34.1% female	Median (IQR) Baricitinib: 61 (51.5-71) Tocilizumab: 62 (51-70)	Hospitalized adults with moderate to severe COVID-19	4 mg dose or administered orally and adjusted	Single dose of 8 mg/kg (max 800 mg) administered	Remdesivir, dexamethasone, prolonged steroid courses	In-hospital mortality, Progression to MV, Adverse events: Thrombosis	None

						based on renal function; once daily for a median of 9 days	IV over 60 minutes	(>10 days), antibiotics		
Roddy 2022	7 hospitals in USA 8/2021-12/2021	Retrospective cohort	382 (188/194); 48.4% female	Mean (SD) Baricitinib: 58.7 (14.6) Tocilizumab: 57.7 (14.7)	Adults ≥18 years with COVID-19 pneumonia, hypoxemia (P/F ratio ≤300), and new treatment with tocilizumab or baricitinib	Orally for 14 days	1-2 doses	Dexamethasone, remdesivir	Mortality; Adverse events: Thromboembolism, hospital-acquired infections (central-line-associated bloodstream infection, catheter-associated urinary tract infection, Clostridium difficile infection, opportunistic infection)	Not reported
Rosas 2020	1 hospital in Spain 3/2020-4/2020	Retrospective cohort	60 (12/20); 28.3% female	Mean (SD) Baricitinib: 67.8 (13.6) Tocilizumab: 59.4 (14.5)	Patients admitted due to interstitial pneumonia secondary to COVID-19 and PaO_2/FiO_2 (ratio between PaO_2 in mmHg and FiO_2 in %) <300	4 mg or 2 mg once daily and administered orally for a mean time in treatment of 4.5 days	Single dose of 400 mg in patients weighing <75 kg or 600 mg in those weighing ≥75 kg administered IV	Hydroxychloroquine, corticosteroids, interferon	Overall mortality since admission (1-15 days); Overall mortality since admission (16-30 days); Adverse events: Neutropenia, thrombotic event, or other relevant side effects	Association for Research in Rheumatology of the Marina Baixa
Sunny 2023	11 hospitals in USA 12/2020-3/2022	Retrospective cohort	1194 (597/597); % female not reported	Mean (SD) Baricitinib: 62.8 (16.1) Tocilizumab: 62.2 (16.4)	Patients hospitalized with COVID-19	Orally and continuously over multiple days	Single dose administered IV	Medical/Surgical, steroids, remdesivir, vasopressors	Mortality, Adverse events: deep vein thrombosis or pulmonary embolism	Not reported
Tomos 2025	2 hospitals in Greece	Retrospective cohort	321 (241/80); 40.8% female	Mean (SD) Baricitinib: 64.2 (15.2) Tocilizumab: 57.3 (11.7)	Patients with severe COVID-19 and increased needs for	4 mg orally and once daily for 14 days	Single dose of 8 mg/kg administered IV	Oxygen support, remdesivir, dexamethasone	Mortality on day 14; Mortality on day 28; High-flow nasal cannula use;	None

	5/2021-7/2022				oxygen, including high-flow nasal cannula (HFNC), noninvasive ventilation (NIV), or s/sx of severe disease				Mechanical ventilation; Adverse events: Drug-induced liver injury, bacterial infection, deep vein thrombosis, acute kidney injury, ACS, hemorrhage, arrhythmia	
Troyer 2024	16 hospitals in USA Dates NR	Retrospective cohort	133 (69/64); % female not reported	Median (IQR) Baricitinib: 58 (55-60) Tocilizumab: 57.5 (46.8-64)	COVID-19 patients requiring ICU-level care and ventilatory support (invasive or non-invasive) and BMI ≥30 kg/m^2	1-4 mg (based on renal parameters) administered orally and once daily for 14 days or until discharge/adverse effects	One dose of 8 mg/kg (max 800 mg) administered IV with a potential repeat in 24 hours	Dexamethasone	In-hospital mortality; Adverse events: Positive blood cultures, fungal infections	None

Supplementary Table 2a. Risk of bias assessment using RoB 2.0 (RCT)

Study	Bias in randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of outcome	Bias in selection of the reported result
Karampitsakos 2023	Low	Low	Low	Low	Some concerns

Table 2b. Risk of bias assessments using ROBINS-I V2 for mortality outcomes (NRS)

Study	Bias due to confounding	Bias in classification of interventions	Bias in selection of participants into the study	Bias due to deviations from	Bias due to missing data	Bias in measurement of the outcome	Bias in selection of the reported result

				intended interventions			
Conroy 2024	Moderate	Low	Low	Low	Low	Low	Low
Karolyi 2023	Critical	Low	Low	Low	Low	Low	Low
Kojima 2022	Serious	Low	Low	Low	Low	Low	Low
Lakatos 2022	Serious	Low	Low	Low	Low	Low	Low
Patanwala 2025	Serious	Low	Low	Low	Low	Low	Low
Peterson 2023	Moderate	Low	Low	Low	Low	Low	Low
Reid 2023	Serious	Low	Low	Low	Low	Low	Low
Roddy 2022	Serious	Low	Low	Moderate	Low	Low	Low
Rosas 2020	Serious	Low	Low	Low	Low	Low	Low
Sunny 2023	Low	Low	Low	Low	Low	Low	Low
Tomos 2025	Critical	Low	Low	Low	Low	Low	Low
Troyer 2024	Serious	Low	Low	Low	Low	Low	Low

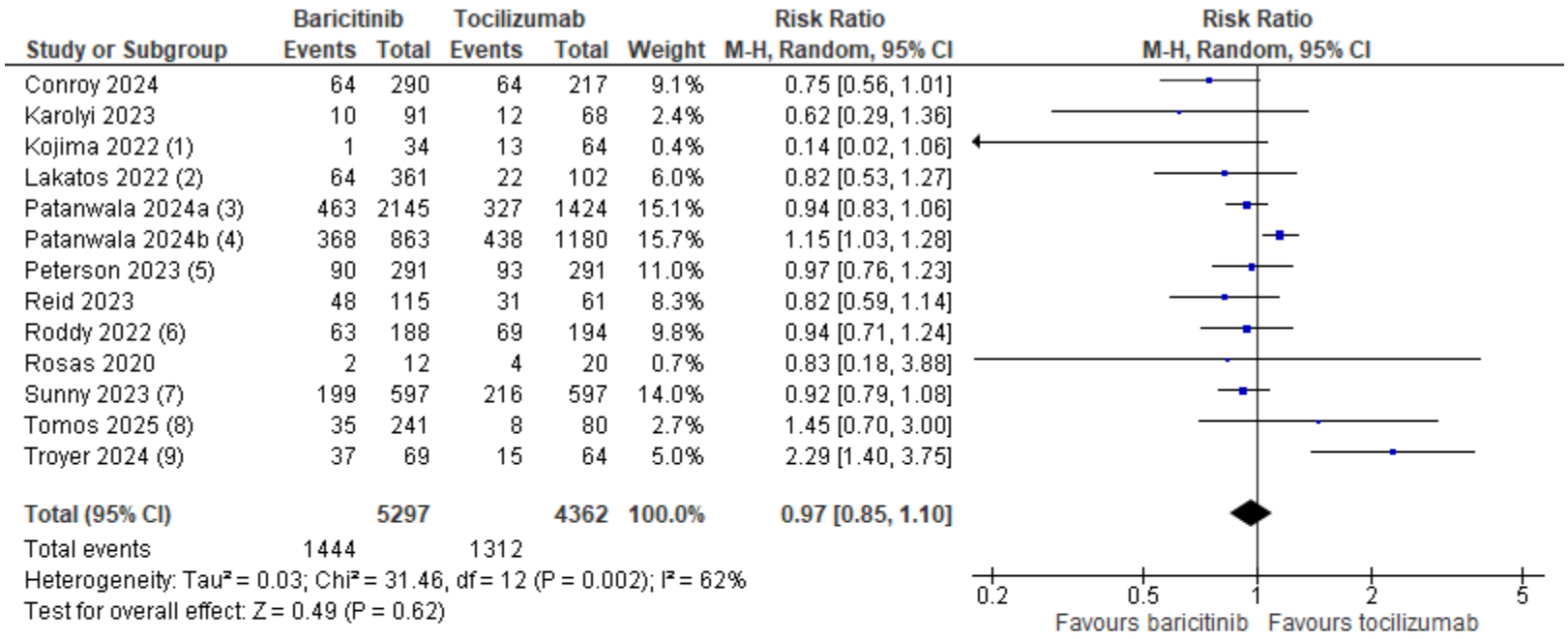
Table 2c. Risk of bias assessments using ROBINS-I V2 for non-invasive ventilation outcomes (NRS)

Study	Bias due to confounding	Bias in classification of interventions	Bias in selection of participants into the study	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of the outcome	Bias in selection of the reported result
Tomos 2025	Critical	Low	Low	Low	Low	Low	Low

Table 2d. Risk of bias assessments using ROBINS-I V2 for mechanical ventilation outcomes (NRS)

Study	Bias due to confounding	Bias in classification of interventions	Bias in selection of participants into the study	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of the outcome	Bias in selection of the reported result
Conroy 2024	Serious	Low	Low	Low	Low	Low	Low
Karolyi 2023	Critical	Low	Low	Low	Low	Low	Low
Lakatos 2022	Serious	Low	Low	Low	Low	Low	Low
Peterson 2023	Moderate	Low	Low	Low	Low	Low	Low
Reid 2023	Serious	Low	Low	Low	Low	Low	Low
Tomos 2025	Critical	Low	Low	Low	Low	Low	Low

Supplementary Figure 2. Baricitinib vs. tocilizumab for the outcome of mortality (NRS)



Footnotes

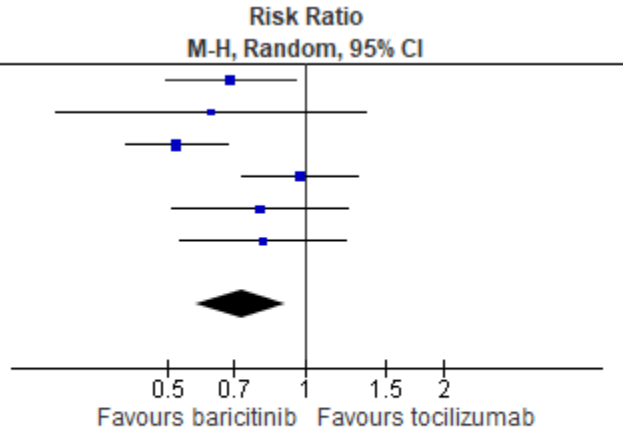
(1) 28d f/u
(2) 28d f/u
(3) NIV; 28d f/u
(4) MV; 28d f/u
(5) Matched cohort
(6) 60d f/u
(7) Matched cohort; 28d f/u
(8) 28d f/u
(9) 14d f/u

Supplementary Figure 3. Baricitinib vs. tocilizumab for the outcome of mechanical ventilation (NRS)

Study or Subgroup	Baricitinib Events	Baricitinib Total	Tocilizumab Events	Tocilizumab Total	Weight	Risk Ratio M-H, Random, 95% CI
Conroy 2024	54	290	59	217	19.4%	0.68 [0.50, 0.95]
Karolyi 2023	10	91	12	68	6.7%	0.62 [0.29, 1.36]
Lakatos 2022	96	361	52	102	22.8%	0.52 [0.40, 0.67]
Peterson 2023 (1)	69	291	71	291	21.1%	0.97 [0.73, 1.30]
Reid 2023	33	115	22	61	14.5%	0.80 [0.51, 1.24]
Tomos 2025	56	241	23	80	15.5%	0.81 [0.53, 1.22]
Total (95% CI)		**1389**		**819**	**100.0%**	**0.72 [0.58, 0.90]**
Total events	318		239			

Heterogeneity: $Tau^2 = 0.04$; $Chi^2 = 11.09$, $df = 5$ ($P = 0.05$); $I^2 = 55\%$

Test for overall effect: $Z = 2.83$ ($P = 0.005$)



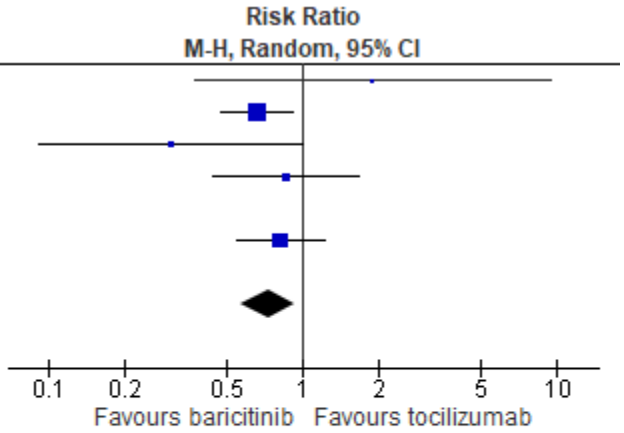
Footnotes

(1) Progression to MV or ECMO

Supplementary Figure 4. Baricitinib vs. tocilizumab for the outcome of adverse events (NRS)

Study or Subgroup	Baricitinib Events	Baricitinib Total	Tocilizumab Events	Tocilizumab Total	Weight	Risk Ratio M-H, Random, 95% CI
Karolyi 2023 (1)	5	91	2	68	2.4%	1.87 [0.37, 9.34]
Peterson 2023 (2)	47	291	71	291	46.4%	0.66 [0.48, 0.92]
Reid 2023 (3)	4	115	7	61	4.3%	0.30 [0.09, 0.99]
Roddy 2022 (4)	15	188	18	194	13.6%	0.86 [0.45, 1.66]
Rosas 2020 (5)	0	12	0	20		Not estimable
Sunny 2023 (6)	40	597	49	597	33.3%	0.82 [0.55, 1.22]
Total (95% CI)		**1294**		**1231**	**100.0%**	**0.73 [0.57, 0.93]**
Total events	111		147			

Heterogeneity: Tau² = 0.01; Chi² = 4.29, df = 4 (P = 0.37); I² = 7%
Test for overall effect: Z = 2.49 (P = 0.01)



Footnotes
(1) Thrombotic event
(2) Matched cohort; Thrombotic events
(3) Thrombosis
(4) Thromboembolism
(5) Neutropenia, thrombotic event
(6) Matched cohort; DVT/PE events

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