Checklist of items for reporting pragmatic trials

Section	Item	Standard CONSORT description	
Title and abstract	1	How participants were allocated to interventions (eg, "random allocation," "randomised," or "randomly assigned")	**Convenience sample of eligible, hospitalized patients as indicated in title and abstract. See Pages 1 &2.**
Introduction			
Background	2	Scientific background and explanation of rationale	**Convalescent plasma represents a promising treatment strategy (for COVID-19) with strong historical precedence, biological plausibility, and limited barriers for rapid development and deployment of this investigational therapy. See Pages 4 &5.**
Methods			
Participants	3	Eligibility criteria for participants; settings and locations where the data were collected	**Eligible patients were aged 18 years or older, hospitalized with a laboratory confirmed diagnosis of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and had, or were judged by a healthcare provider to be at high risk of progression to, severe or life-threatening COVID-19. See Page 14.**
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	**Convalescent plasma (200 – 500 mL) was administered intravenously according to institutional transfusion guidelines. See Page 14.**
Objectives	5	Specific objectives and hypotheses	**Thus, we analyzed key safety metrics following transfusion of convalescent plasma in 5,000**

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			hospitalized adults with severe or life threatening COVID 19. We hypothesized that the rate of serious adverse events related to the transfusion of convalescent plasma per se would be low and that the seven-day mortality rate would not be demonstrably elevated compared to other experiences with this deadly disease. See Page 5.
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors)	**Thus, we analyzed key safety metrics following transfusion of convalescent plasma in 5,000 hospitalized adults with severe or life-threatening COVID-19. See Page 5.**
Sample size	7	How sample size was determined; explanation of any interim analyses and stopping rules when applicable	**N/A. Enrollment and data accrual are on-going in this Expanded Access Program. See Figure 1.**
Randomisation—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)	**N/A. Convenience sample without allocation. See Page 13.**
Randomisation—allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned	**N/A. Convenience sample without allocation. See Page 13.**
Randomisation—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups	**N/A. Convenience sample without allocation. See Page 13.**
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	**N/A. No blinding or masking. See Page 13.**

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Statistical methods	12	Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses	**N/A. Presentation of key safety metrics within one group. See Page 15.**
Results			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons	**N/A.**
Recruitment	14	Dates defining the periods of recruitment and follow-up	**N/A. Enrollment and data accrual are on-going in this Expanded Access Program. See Figure 1.**
Baseline data	15	Baseline demographic and clinical characteristics of each group	**See Table 1, Page 22.**
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (eg, 10/20, not 50%)	**5,000 patients.**
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI)	**See Table 1, Page 23.**
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory	**N/A.**

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Adverse events	19	All important adverse events or side effects in each intervention group	**See Table 1, Page 23.**
Discussion			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	**In summary, the experience from the first 5000 patients with COVID-19 transfused with convalescent plasma provides no signal of toxicity beyond what is expected from plasma use in severely ill patients. See Page 12.**
Generalisability	21	Generalisability (external validity) of the trial findings	**Given the accelerating deployment of this therapy, these emerging data provide early safety indicators of convalescent plasma for COVID-19 treatment and suggest research should shift focus toward determining the efficacy of convalescent plasma. See Page 12.**
Overall evidence	22	General interpretation of the results in the context of current evidence	**In summary, the experience from the first 5000 patients with COVID-19 transfused with convalescent plasma provides no signal of toxicity beyond what is expected from plasma use in severely ill patients. See Page 12.**

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