41<79 mg/L, HR:1.60; 79<137 mg/L, HR: 2.12; >137 mg/L, HR: 1.17). The incidence of IMV, ECMO, or death was reduced (OR: 0.31; 95%CI: 0.15–0.63, $p=0.002$) and mortality was improved by 2.22-fold (OR: 2.22; 95%CI: 1.07–4.67, $p=0.034$). In these participants, lenzilumab decreased CRP as early as Day 2 following treatment, compared with placebo which was further decreased by 38% on Day 28 compared with placebo (24.4 ± 3.4 mg/L vs 39.1 ± 4.9 mg/L).

Conclusion Lenzilumab significantly improved SWOV in hospitalized, hypoxic participants with COVID-19 pneumonia with the greatest benefits in SWOV and survival in patients with CRP<150 mg/L and age <85 years. Inhibition of GM-CSF, an orchestrator of CS, early in the hyperinflammatory response improved outcomes in COVID-19. NCT04351152

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A RANDOMISED CLINICAL TRIAL OF AZITHROMYCIN VERSUS STANDARD CARE IN AMBULATORY COVID-19 – THE ATOMIC2 TRIAL

¹TSC Hinks, ¹L Cureton, ¹R Knight, ¹A Wang, ¹JL Cane, ¹VS Barber, ¹J Black, ¹SJ Dutton, ²J Melhorn, ¹M Jabeen, ³P Moss, ⁴R Garlapati, ⁵T Baron, ⁶G Johnson, ⁷F Cantle, ⁸D Clarke, ⁹S Elkhodair, ¹⁰J Underwood, ¹¹D Lasserson, ¹ID Pavord, ¹SB Morgan, ¹D Richards. ¹University of Oxford, Oxford, UK; ²University Hospital Llandough, Cardiff, UK; ³St George's Hospital, Tooting, London, UK; ⁴East Lancashire NHS Hospitals, Blackburn, UK; ⁵Oxford University Hospitals NHS Foundation Trust, Oxford, UK; ⁶University Hospitals of Derby and Burton, Derby, UK; ⁷Kings College Hospital, London, UK; ⁸Royal Berkshire Hospital, Reading, UK; ⁹University College London Hospital, London, UK; ¹⁰Cardiff and Vale University Health Board, Cardiff, UK; ¹¹City Hospital, Birmingham, UK

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Background The antibacterial, anti-inflammatory and antiviral properties of azithromycin suggest therapeutic potential against COVID-19. Randomised data in mild-moderate disease are lacking. We assessed whether azithromycin is effective in reducing hospitalisation in patients with mild-moderate COVID-19.

Methods This open-label, randomised superiority clinical trial at 19 centres in the United Kingdom enrolled adults, ≥ 18 years, presenting to hospitals with clinically-diagnosed highly-probable or confirmed COVID-19 infection, with <14 days symptoms, considered suitable for initial ambulatory management. Patients were randomised (1:1) to azithromycin (500 mg daily orally for 14 days) or to standard care without macrolides. The primary outcome was the difference in proportion of participants with death or hospital admission from any

Abstract S50 Figure 1 Kaplan-Meier plot of time to hospitalisation in the ITT +ve population

cause over the 28 days from randomisation, assessed according to intention-to-treat (ITT). Trial registration: ClinicalTrials.gov, NCT04381962, Study closed.

Results 298 participants were enrolled from 3rd June 2020 to 29th January 2021. The primary outcome was assessed in 292 participants. The primary endpoint was not significantly different between the azithromycin and control groups (Adjusted OR 0.91 [95% CI 0.43–1.92], $p=0.80$).

Conclusions In patients with mild-moderate COVID-19 managed without hospital admission, adding azithromycin to standard care treatment did not reduce the risk of subsequent hospitalisation or death. Our findings do not support the use of azithromycin in patients with mild-moderate COVID-19.

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EVALUATION OF TREATMENT APPROACHES FOR HOSPITALIZED COVID-19 PATIENTS

A Kilcoyne, E Jordan, C Durrant, D Chappell, O Ahmed. Humanigen, Inc., Burlingame, CA, USA

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Background COVID-19 has driven innovation leading to emergency use authorization of treatments that address its urgent healthcare needs. However, physicians, payers and healthcare systems are challenged to select among these novel treatments for both effectiveness and value. Reliance on change in relative, rather than absolute, risk often makes discrimination of treatment effects between medications impractical, with potentially misleading conclusions. Number Needed to Treat (NNT), the reciprocal of the Absolute Risk Reduction, can be a valuable alternative in assessing benefit:risk. The objective of the current analysis was to calculate NNT for reported endpoints of COVID-19 treatments.

Methods Clinical information was captured from published literature and pre-prints from investigations of COVID-19 treatments. NNTs were calculated for reported endpoints. Outpatient treatments to reduce viral load included neutralizing antibody ‘cocktails’ REGN-COV2¹ and bamlanivimab/etesevimab.² Inpatient treatments included the anti-viral: remdesivir^{3,4}; and immune modulators: baricitinib⁵, and lenzilumab.⁶

Results REGN-COV2 reduced the number of medically attended visits with NNT of 33.3. The NNT for hospitalization or death was 20 for bamlanivimab/etesevimab. NNTs for 28-day mortality with inpatient treatment were 37 for baricitinib, 26.3 for remdesivir alone, and 22.7 for lenzilumab. Additional analyses of lenzilumab resulted in NNT of 14.7 when combined with remdesivir and corticosteroids, 15.4 when combined with remdesivir, and 13.9 in patients with baseline CRP<150mg/L and age<85 years. The NNT for lenzilumab to prevent survival without ventilation (SWOV) was 15.4 which, decreased to 6.4 in patients with baseline CRP<150mg/L and age<85 years. The number needed to prevent a serious adverse event was 20 for baricitinib, 15 for remdesivir, and 20.4 for lenzilumab.

Conclusion The NNT for COVID-19 treatments varied with setting, endpoint, and mechanism. The NNT for lenzilumab improved with refinement of concomitant medications and patient phenotype. NNT provides a simple measure for comparative analyses that helps inform clinical decision-making and resource allocation.

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