Conclusion: In a global, diverse population of patients with severe COVID-19 pneumonia and hyperinflammation receiving supplemental oxygen therapy, corticosteroids, and remdesivir, a single infusion of mavrilimumab reduced progression to mechanical ventilation and improved survival. Results indicate mavrilimumab, a potent inhibitor of GM-CSF signaling, may have added clinical benefit on top of the current standard therapy for COVID-19. Of potential importance is that this treatment strategy is mechanistically independent of the specific virus or viral variant.

REFERENCES:


DOI: 10.1136/annrheumdis-2021-eular.5012
severe adverse events, namely a case of hemiparesis in a patient with systemic sclerosis/SLE overlap syndrome (ongoing at the time of reporting), and a case of giant cell arteritis in a patient with osteoarthritis (recovered/resolved without sequelae).

**Conclusion:** The safety profiles for COVID-19 vaccines in RMD patients was reassuring. Most adverse events were the same as in the general population, they were non-serious and involved short term local and systemic symptoms. The overwhelming majority of patients tolerated their vaccination well with rare reports of inflammatory RMD flare (5%; 1.2% severe) and very rare reports of severe adverse events (0.1%). These initial findings should provide reassurance to rheumatologists and vaccine recipients, and promote confidence in COVID-19 vaccine safety in RMD patients, namely those with inflammatory RMDs and/or taking treatments that influence their immune system.

**Acknowledgements:** EUROL COVID-19 Task Force; European Reference Network on rare and Complex Connective Tissue and Musculoskeletal Diseases; European Reference Network on Rare Immunodeficiency; Autoimmune and Autoimmune Diseases Network; all rheumatologists contributing to the EUROL COVAX Registry.

**Disclosure of Interests:** Pedro M Machado Consultant of: Abbvie, BMS, Celgene, Eli Lilly, Janssen, MSD, Novartis, Orphazyme, Pfizer, Roche and UCB, all unrelated to this manuscript., Grant/research support from: Roche, unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Eli Lilly, Janssen, MSD, Novartis, Orphazyme, Pfizer, Roche and UCB, all unrelated to this manuscript., Saskia Lawesson Tovey: None declared, Kimmy Hyrich Consultant of: BMS, UCB, and Pfizer, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Sanofi, SigmaBioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Sanofi, Galapagos, all unrelated to this manuscript., Elsa Mateus Consultant of: her institute works by contract for laboratories among other institutions, such as Abbvie Spain, Eisai, Genworth, Menk Sharp & Dohme España, S.A., Novartis Farmaceutica, Pfizer, Roche Farma, Sanofi Aventis, Astellas Pharma, Actelion Pharmaceuticals España, Grünenthal GmbH, and UCB Pharma, all unrelated to this manuscript., Laure Goeze Consultant of: Abbvie, BMS, Celgene, Gilead, Janssen, Novartis, Pfizer, SigmaBioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., BERND RAFFEINER: None declared, Elsa Mateus Consultant of: her institute works by contract for laboratories among other institutions, such as Abbvie Spain, Eisai, Genworth, Menk Sharp & Dohme España, S.A., Novartis Farmaceutica, Pfizer, Roche Farma, Sanofi Aventis, Astellas Pharma, Actelion Pharmaceuticals España, Grünenthal GmbH, and UCB Pharma, all unrelated to this manuscript., Laure Goeze Consultant of: Abbvie, BMS, Celgene, Gilead, Janssen, Novartis, Pfizer, SigmaBioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript., Speakers bureau: Abbvie, BMS, Celgene, Gilead, Eli Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, all unrelated to this manuscript.

**Objectives:** To investigate the immunogenicity, efficacy, and safety of the BNT162b2 mRNA vaccine in patients with AIIRD compared to the general population.

**Methods:** A prospective multicenter study investigated immunogenicity, efficacy, and safety of the two-dose regimen BNT162b2 mRNA vaccine in adult patients with AIIRD including rheumatoid arthritis (RA), psoriatic arthritis (PsA), axial spondyloarthritis (axSpA), systemic lupus erythematosus (SLE), connective tissues diseases (CTD), systemic vasculitides, and idiopathic inflammatory myositis (iIM), compared to control subjects without rheumatic diseases or immunosuppressive therapies. Serum IgG antibody levels against SARS-CoV-2 spike S1/S2 proteins were measured 2 - 6 weeks after the second vaccine dose. Seropositivity was defined as IgG ≥15 binding antibody units (BAU)/ml. Post-vaccination efficacy defined as post-vaccination COVID-19 infection and safety were assessed. Pre- and post-vaccination disease activity indices were assessed as appropriate for each disease.

**Results:** A total of 686 AIIRD patients and 121 controls participated into the study. AIIRD patients were significantly older than controls, mean ages SD 56.76±14.88 vs 50.76±14.68, respectively, p<0.0001. A total of 95.2% (n=653) AIIRD patients were treated with immunomodulatory medications.

The seropositivity rate was 86% (n=590) in patients with AIIRD compared to 100% in controls (p <0.0001) The level of the S1/S2 antibodies was significantly reduced in AIIRD patients compared to controls (mean± SD 132.9±91.7 vs 218.6±82.06, P<0.0001). In patients with PsA, AxSpA, SLE, and LVM, the seropositive rate was above 90%. In RA, the seropositive rate was 82.1% and the lowest seropositive rate (-40%) was observed in patients with AAV and IM. Anti-CD20 significantly impaired the vaccine’s immunogenicity, with the lowest seropositive rate of 39%. The use of GC, mycophenolate mofetil (MMF), and abatacept was associated with a significantly lower rate of seropositivity (Figure 1). MTX significantly reduced the seropositivity in patients treated with MTX monotherapy and in combinations with other treatments (92% and 84%, respectively), although at a lesser magnitude than anti-CD20, MMF, and abatacept. More than 87% of patients treated with anti-cytokine therapies including TNFi, interleukin-17 and interleukin-6 inhibitors had an appropriate immunogenic response when used as monotherapy. The combination of TNFi with MTX significantly reduced the rate of seropositivity to 93%, p=0.04. Age over 65 years, a diagnosis of RA, IM, ANCA-associated vasculitis, and treatment with GC, MMF, anti-CD20, and abatacept were associated with a reduced likelihood of seropositivity.

**Figure 1.** Seropositivity rate by immunosuppressive treatment. There were no post-vaccination symptomatic cases of COVID-19 among AIIRD patients and one mild case in the control group. Major adverse events in AIIRD patients included death (n=2) several weeks after the second vaccine dose, non-disseminated herpes zoster (n=6), uveitis (n=2), and pericarditis (n=1). Post-vaccination disease activity remained stable in the majority of patients.

**Conclusion:** Vaccination with the BNTt262 vaccine resulted in an adequate immunogenic response with an acceptable safety profile in the majority of patients with AIIRD. Treatment with GC, rituximab, MMF, and abatacept may impair BNT162b2-induced immunogenicity. Postponing administration...