NEW STUDY DEBUNKS THEORETICAL RISKS OF LIVE-ATTENUATED VACCINES IN CHILDREN WITH RHEUMATIC DISEASES

Study reports no vaccine infections in children given live-attenuated booster vaccine while on immune suppressing therapies¹

Madrid, Spain, 13 June 2019: The results of a study presented today at the Annual European Congress of Rheumatology (EULAR 2019), jointly organised with the Paediatric Rheumatology Society (PReS), demonstrate no vaccine infections, and no disease flare, in the 234 rheumatic patients who received live-attenuated booster vaccination while taking immune suppressing therapies.¹

There are estimated to be over 75,000 children living with rheumatic diseases in Europe.² Safe and effective vaccination is crucial given their increased risk of infections, however, in patients who are on high doses of therapies that suppress the immune system, it is currently recommended to withhold live-attenuated vaccines (although this can be considered on a case-to-case basis). This is due to a theoretical, but not proven, risk of developing the infection.³ Live-attenuated vaccines contain viruses or bacteria that have been weakened, but not destroyed, in a laboratory. They cannot cause disease in healthy people but can still produce a strong immune response.⁴

Some doctors already vaccinate their patients with rheumatic disease on immune suppressing therapies with the live-attenuated MMR (measles, mumps, rubella) or MMRV (MMR, varicella) booster. This is because, in light of recent measles epidemics in Europe and in the US, they feel the theoretical risk of vaccination is much lower than the risk of disease. This study identified 234 such patients from 13 centres across 10 countries and found no vaccine infections and low rates of adverse events.¹

“Patients with rheumatic and musculoskeletal diseases have an increased risk of infection and so it is vital to vaccinate where possible to save lives,” said Professor Hans Bijlsma, President, EULAR. “There is a lot of ‘fake news’ surrounding vaccination in the media and online and therefore we welcome these data presented today which should help dispel some of the public worries.”

In the study presented today, the live-attenuated MMR or MMRV booster vaccine was given to 110 cases on methotrexate with three reporting mild injection-site reactions, 76 cases on methotrexate plus anti-tumour necrosis factor (anti-TNF) with seven reporting mild transient AEs; and 39 cases on anti-TNF alone with one reporting fever. Other biologic therapies were used on the remaining patients, three were on tocilizumab, seven on anakinra, and five on canakinumab. The mean age of patients in the study was five years, 70% of patients were
The vast majority had juvenile idiopathic arthritis (n=206) with disease activity considered low, moderate and high in 38%, 7% and 2% respectively.¹

“The positive results of our study suggest live-attenuated MMR and MMRV booster vaccination is safe in children with rheumatic diseases,” said Prof. Yosef Uziel, pediatric department, Meir Medical Center, Sackler School of Medicine, Tel Aviv University, and PreS working party on vaccination, Israel. “Current recommendations are cautious due to low levels of evidence and so we are launching a prospective study on safety and efficacy of MMR booster vaccine in paediatric rheumatology patients treated with immunosuppressive therapy, including biological therapy.”

The flu vaccine is not live-attenuated and is recommended in all patients affected by rheumatoid arthritis, regardless of treatment. However, there is data showing that patients are not being vaccinated as recommended and hence putting themselves at risk.⁵

The first real-world study of the flu vaccine in patients with autoimmune rheumatic diseases (AIRDs) was presented today at EULAR 2019. The study included 14,928 AIRD cases and found no association between the flu vaccine and disease activity, prescription of corticosteroid, or vasculitis. In fact, results demonstrate the flu vaccine is associated with a significant reduction in fatigue in the 2-3 months post vaccination, and a significant reduction in primary-care consultations for joint pain in the three months post-vaccination period.⁶

“Our results clearly support the use of the flu vaccine in rheumatic patients and should dispel any fears people have about reported links to disease activity or vasculitis,” said Dr. Georgina Nakafero, Academic Rheumatology, University of Nottingham.

Another reason cited for not vaccinating against flu in patients with rheumatic diseases taking immune suppressing therapies is that, because the body has a weakened immune system, the response to the vaccine may not be big enough to protect the patient from a subsequent flu infection.

A third study, also presented today during EULAR 2019, reveals that, in order to prevent one case of flu, you only need to vaccinate 10 people with rheumatoid arthritis on a tumour necrosis factor inhibitor whereas you need to vaccinate 71 healthy individuals. This is because, although the immunity developed in response to the vaccine may not be as strong in these patients, their increased risk of infection means more cases are prevented.⁷

“Our analysis provides further evidence on the effectiveness of flu vaccination in patients affected by rheumatoid arthritis receiving treatment with tumour necrosis factor inhibitors and should represent a call-to-action for all rheumatologists to consider vaccination in such patients,” said Dr. Giovanni Adami, University of Verona, Rheumatology Unit.

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NOTES TO EDITORS
For further information on this study, or to request an interview with the study lead, please do not hesitate to contact the EULAR Press Office:

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About Rheumatic and Musculoskeletal Diseases
Rheumatic and musculoskeletal diseases (RMDs) are a diverse group of diseases that commonly affect the joints, but can affect any organ of the body. There are more than 200 different RMDs, affecting both children and adults. They are usually caused by problems of the immune system, inflammation, infections or gradual deterioration of joints, muscle and bones. Many of these diseases are long term and worsen over time. They are typically painful and limit function. In severe cases, RMDs can result in significant disability, having a major impact on both quality of life and life expectancy.8

About ‘Don't Delay, Connect Today!’
‘Don’t Delay, Connect Today!’ is a EULAR initiative that unites the voices of its three pillars, patient (PARE) organisations, scientific member societies and health professional associations - as well as its international network - with the goal of highlighting the importance of early diagnosis and access to treatment. In the European Union alone, over 120 million people are currently living with a rheumatic disease (RMD), with many cases undetected.9 The ‘Don’t Delay, Connect Today!’ campaign aims to highlight that early diagnosis of RMDs and access to treatment can prevent further damage, and also reduce the burden on individual life and society as a whole.

About EULAR
The European League against Rheumatism (EULAR) is the European umbrella organisation representing scientific societies, health professional associations and organisations for people with RMDs. EULAR aims to reduce the burden of RMDs on individuals and society and to improve the treatment, prevention and rehabilitation of RMDs. To this end, EULAR fosters excellence in education and research in the field of rheumatology. It promotes the translation of research advances into daily care and fights for the recognition of the needs of people with RMDs by the EU institutions through advocacy action.

To find out more about the activities of EULAR, visit: www.eular.org

References
1 Uziel Y, Bergonzo VM, Onozo B, et al. Live attenuated vaccines in pediatric rheumatic diseases are safe: multi-center, retrospective data collection. EULAR 2019; Madrid: Abstract OP0205

4 NHS. Vaccine ingredients. Available at: https://www.nhs.uk/conditions/vaccinations/vaccine-ingredients/ [Last accessed May 2019]


8 van der Heijde D, Dalkh DI, Betteridge N, et al. Common language description of the term rheumatic and musculoskeletal diseases (RMDs) for use in communication with the lay public, healthcare providers and other stakeholders endorsed by the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR). *Ann Rheum Dis.* 2018 Jun;77(6):829-832.

9 EULAR. 10 things you should know about rheumatic diseases fact sheet. Available at: https://www.eular.org/myUploadData/files/10%20things%20on%20RD.pdf [Last accessed May 2019].