Vaccination against SARS-CoV-2 in people with psoriatic disease
EuroGuiDerm statement

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Vaccination against SARS-CoV-2 is of major importance for people with psoriasis disease. The following text summarizes the current recommendations by the STIKO (the German Committee for Vaccination Guidance) [1] for vaccination and evidence currently available (March 2021).

What do we know about the characteristics of currently available vaccines?
In a very short time, several different vaccines licensed for active immunization against the new corona virus SARS-CoV 2 infection became available and there are more to come. All vaccines provide a high level of protection for COVID19. Despite this huge achievement to fight the infection and to end the pandemic it is debated if vaccination can be recommended for those suffering from chronic, immunologically mediated inflammatory disorders such as psoriasis or psoriatic arthritis, or if current treatment is a reason to postpone vaccination. General recommendations for vaccination against SARS-CoV2 have been published[1].

Because mRNA (messenger ribonucleic acid)-based vaccines are used for the first time, the debate as to whether sufficient protective immunity can be achieved for longer periods of time and, whether this particular mode of vaccination may result in not yet known adverse effects, is ongoing.

As of March 2021, four vaccines are approved in the European Union that can be used in patients with psoriasis disease. There are two similar mRNA (BioNtech-Pfizer and Moderna) and two vector-based vaccine (AstraZeneca and Johnson&Johnson). Both mRNA-based vaccines contain an mRNA coding for the production of the entire spike-protein of SARS-CoV-2 protected from degradation by a lipid membrane that further enables penetration into cells. According to the manufacturer's recommendation, these vaccines should be injected intramuscular to enable muscle cells and others to produce and to release viral

spike protein that can be recognized as antigen. Subsequently, a cellular and antibody-dependent immune reaction is induced. The vaccines by AstraZeneca and Johnson&Johnson are based on adenovirus viral vectors that are non-pathogenic for humans, carrying the SARS-CoV-2 viral spike-protein coding gene enabling vaccinated human host cells to produce spike protein and in the immune system recognition. None of the vaccines are live-attenuated [2].

Efficacy and safety data of a phase 2/3 study have been published for the BioNtech-Pfizer vaccine BNT162b2 on the basis of 43.548 randomized participants (>16 years of age) of which 21.720 received 2 doses of the vaccine (30 microgram) within 3 weeks and 21.728 participants receiving placebo[3]. The mean follow-up time was 2 months after the second dose. The level of protection was 95%. Local injection-site reactions were the most frequent adverse events as well as flu-like symptoms. All reported adverse events were similar to those reported for already established vaccines. Newly described adverse events were not observed within the observation time. Similar data efficacy data were published for the vaccine mRNA-1273 from Moderna, but no safety data is available yet[4].

Published data for the vaccine AZD1222 from AstraZeneca demonstrated, in an interim analysis of 11.636 participants, a level of protection of 90% after the first application with half of the dose and a second application 4 weeks later with the standard dose[5]. In this study adverse events were similar to those observed with established vaccines within a mean follow-up of 3.4 months. Theoretically it is possible that with this vaccine immune reaction against the adenovirus-vector may be seen after the second dose potentially reducing vaccination response.

First data of an interim analysis of the Johnson&Johnson vaccine phase 1–2a trial showed an acceptable safety and reactogenicity profile of the Ad26.COV2.S vaccine after a single vaccination with either the low or high dose. There was a trend towards an increase rate of adverse events in the high-dose group (Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine [6]).

The data show high efficacy and favorable safety of all vaccines. New safety signals have not been observed within the relatively short follow-up period. Initial data provide evidence that

the BioNtech-Pfizer vaccine induces protective antibodies against viral mutants (eg. British- and South-African mutants) and is, in principle, effective[7]. The value of vaccines to decrease viral transmission is still uncertain.

Should patients undergoing systemic therapy for psoriatic disease be vaccinated?

Because people with psoriasis disease or psoriatic arthritis have numerous risk factors (eg. obesity, hypertension, diabetes, and cardiac insufficiency) for severe courses of COVID19 the vaccination is recommended[8]. There is no reason to believe that there is a negative impact on psoriasis and psoriatic arthritis due to the mode of action of the mRNA- and the vector-based vaccines. As patients on immunosuppressive therapies were excluded from the clinical trials, there is currently no data on the efficacy and safety of SARS-CoV-2 vaccines in those treated with conventional or biologic disease modifying antirheumatic drugs. However, in terms of safety, the vaccines are expected to be safe in psoriasis patients on systemic therapy given that they are not live-attenuated vaccines. In terms of efficacy, immunosuppressant treatments could to some extent reduce the efficacy of vaccines. In case of treatment with ciclosporin and methotrexate there may be a reduced vaccination response[9], and a short interruption of the drug could be considered (maybe for 5 pharmacological half-lives). No conclusive data is available to evaluate a potential effect of systemic immunomodulating/immunosuppressive treatments on Sars-CoV-2 vaccination response. Vaccine interactions with systemic therapies approved for psoriasis and psoriatic arthritis are unlikely and the association is not contraindicated in the SPCs of these vaccines. Weighing the potential benefits and risks, we suggest providing SARS-CoV-2 vaccination for all psoriatic patients on systemic treatment because, although they might show to be not as effective as in healthy individuals, in selected cases, they may still provide some degree of protection against COVID19[10]. Therefore, patients under treatment can be vaccinated. These recommendations will be updated periodically related to the availability of new data. Because of the rapidly changing evidence base new developments should be considered.

In summary:

1. It is recommended to vaccinate people with psoriatic disease with the approved vaccines. In terms of safety, the 4 currently licensed vaccines are expected to be safe in psoriasis patients on immunosuppressants given that they are not live-attenuated vaccines. Related systematic data are to be expected within the following months.
2. During the phase of vaccination, psoriasis treatment with any approved medication should not be interrupted. If feasible, it is recommended to plan vaccination in the middle of the interval between two applications of the drug. Exceptions may be treatment with ciclosporin, methotrexate, or tofacitinib for which a short interruption of therapy can be considered.
3. A full protection from vaccination is not guaranteed for every person. Until today it is unclear whether vaccinated people can transmit the virus. Therefore, all measures for prevention of viral spreading (eg. wearing masks, keeping distance) should be in place.
4. People with psoriasis should be receiving other vaccines such as against influenza and pneumococci as recommended.

References

[1] STIKO. Beschluss der STIKO für die Empfehlung der COVID-19-Impfung und die dazugehörige wissenschaftliche Begründung: STIKO-Empfehlung zur COVID-19-Impfung. Epidemiologisches Bulletin 2 2021 14. Januar 2021 (online vorab)

[2] Sharma O, Sultan AA, Ding H, Triggle CR. A Review of the Progress and Challenges of Developing a Vaccine for COVID-19. Front Immunol. 2020 Oct 14;11:585354. doi: 10.3389/fimmu.2020.585354

[3] Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC; C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 10. doi: 10.1056/NEJMoa2034577

[4] Widge AT, Rouphael NG, Jackson LA, Anderson EJ, Roberts PC, Makhene M, Chappell JD, Denison MR, Stevens LJ, Pruijssers AJ, McDermott AB, Flach B, Lin BC, Doria-Rose NA, O'Dell S, Schmidt SD, Neuzil KM, Bennett H, Leav B, Makowski M, Albert J, Cross K, Edara VV, Floyd K, Suthar MS, Buchanan W, Luke CJ, Ledgerwood JE, Mascola JR, Graham BS, Beigel JH; mRNA-1273 Study Group. Durability of Responses after SARS-CoV-2 mRNA-1273 Vaccination. N Engl J Med. 2020 Dec 3. doi: 10.1056/NEJMc2032195

[5] Ramasamy MN, Minassian AM, Ewer KJ, Flaxman AL, Folegatti PM, Owens DR, Voysey M, Aley PK, Angus B, Babbage G, Belij-Rammerstorfer S, Berry L, Bibi S, Bittaye M, Cathie K, Chappell H, Charlton S, Cicconi P, Clutterbuck EA, Colin-Jones R, Dold C, Emary KRW, Fedosyuk S, Fuskova M, Gbesemete D, Green C, Hallis B, Hou MM, Jenkin D, Joe CCD, Kelly EJ, Kerridge S, Lawrie AM, Lelliott A, Lwin MN, Makinson R, Marchevsky NG, Mujadidi Y, Munro APS, Pacurar M, Plested E, Rand J, Rawlinson T, Rhead S, Robinson H, Ritchie AJ, Ross-Russell AL, Saich S, Singh N, Smith CC, Snape MD, Song R, Tarrant R, Themistocleous Y, Thomas KM, Villafana TL, Warren SC, Watson MEE, Douglas AD, Hill AVS, Lambe T, Gilbert SC, Faust SN, Pollard AJ; Oxford COVID Vaccine Trial Group. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. Lancet. 2021 Dec 19;396(10267):1979-1993.

[6] Sadoff J, Le Gars M, Shukarev G, Heerwegh D, Truyers C, de Groot AM, Stoop J, Tete S, Van Damme W, Leroux-Roels I, Berghmans PJ, Kimmel M, Van Damme P, de Hoon J, Smith W, Stephenson KE, De Rosa SC, Cohen KW, McElrath MJ, Cormier E, Scheper G, Barouch DH, Hendriks J, Struyf F, Douoguih M, Van Hoof J, Schuitemaker H. Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine. N Engl J Med. 2021 Jan 13:NEJMoa2034201. doi: 10.1056/NEJMoa2034201.

[7] Liu Y, Liu J, Xia H, Zhang X, Fontes-Garfias CR, Swanson KA, Cai H, Sarkar R, Chen W, Cutler M, Cooper D, Weaver SC, Muik A, Sahin U, Jansen KU, Xie X, Dormitzer PR, Shi PY. Neutralizing Activity of BNT162b2-Elicited Serum - Preliminary Report. N Engl J Med. 2021 Feb 17. doi: 10.1056/NEJMc2102017

[8] O'Hearn M, Liu J, Cudhea F, Micha R, Mozaffarian D. Coronavirus Disease 2019 Hospitalizations Attributable to Cardiometabolic Conditions in the United States: A Comparative Risk Assessment Analysis. J Am Heart Assoc. 2021 Feb 25:e019259.

[9] Chiricozzi A, Gisondi P, Bellinato F, Girolomoni G. Immune Response to Vaccination in Patients with Psoriasis Treated with Systemic Therapies. Vaccines (Basel). 2020 Dec 16;8(4):769.

[10] Geisen UM, Berner DK, Tran F, Sümbül M, Vullriede L, Ciripoi M, Reid HM, Schaffarzyk A, Longardt AC, Franzenburg J, Hoff P, Schirmer JH, Zeuner R, Friedrichs A, Steinbach A, Knies C, Markewitz RD, Morrison PJ, Gerdes S, Schreiber S, Hoyer BF. Immunogenicity and safety of anti-SARS-CoV-2 mRNA vaccines in patients with chronic inflammatory conditions and immunosuppressive therapy in a monocentric cohort. Ann Rheum Dis. 2021 Mar 24:annrheumdis-2021-220272. doi: 10.1136/annrheumdis-2021-220272.