

Frequently asked questions

COVID-19 vaccines and SAID



General considerations

RNA vaccines are recommended for high-risk SAID patients regardless of age.

There is **no known increase in the risk** of the following effects of vaccination in patients with SAID. Vaccination can even be done at the initiation of treatment if your referring doctor deems necessary.

To date, there is no need to systematically vaccinate patients who have already developed a symptomatic form of COVID-19. If there are risk factors for severe forms, vaccination should be offered if the patient so wishes after discussion with the doctor. In this case, it seems preferable to respect a minimum delay of 3 months after the onset of symptoms of COVID-19.

A good strategy is to vaccinate those around immuno-compromised patients to avoid any unfortunate contamination



Specific questions

From what age can people be vaccinated?

The COVID vaccines have been tested in adults aged 16-18 years and older, including elderly people.

What are the various vaccines available and what are the differences?

Presently, there are 2 kinds of vaccines: the <u>ARN vaccines</u> (i.e. Pfizer-BioNtech, Moderna) and the <u>Adenoviral vaccines</u> (i.e. Astra Zeneca).

The ARN vaccines are based on the administration of a certain amount of RNA (a small nucleic molecule which encodes for the COVID spike protein and is not able to be integrated in our genes) intra-muscularly. This will induce the production of a large amount of COVID spike protein (without any deleterious effect) and enable the development of antibodies against this protein and the SARS-COV-2 itself (the virus at the origin of the COVID 19 pandemic).

The adenovirus vaccine is based on the administration of a non-replicative and non-infective adenovirus (i.e. the virus cannot infect the cells or multiply) intra-muscularly. The following steps are the same, i.e. the injected vaccine will produce a large amount of COVID spike protein and enable the development of antibodies against the SARS-COV-2.

Both vaccines have been associated with interesting rates of anti-SARS-COV2 protection, i.e. between 75 and 95% of people with protective levels of antibodies neutralizing the virus. All vaccines have demonstrated their ability to prevent the serious forms of the COVID-19, i.e. COVID-19 manifestations that make necessary hospitalization in intensive care unit. Recent data seem to indicate that the vaccines have demonstrated their efficacy against the native SARS-COV-2 as well as the UK and South African mutants for ARN vaccines, against the native as well as the UK mutant for the adenovirus vaccine (efficacy against the South African mutants is pending).

What vaccine is safe (inactive) for patients with autoinflammatory diseases?

The safety of the different vaccines has been checked and validated by multiple medical agencies worldwide. The main side effects of the vaccines are a local inflammatory reaction at the injection site (mild to moderate pain, skin redness) and flu-like episodes (fever, aches, fatigue) the day after the injection. Usually, these reactions last less than 24 hours.

People living with autoinflammatory diseases can be vaccinated with any of these vaccines, which are not contraindicated in such patients, whatever their treatment (including immunomodulating or immunosuppressive treatments).

The only concern is about the effectiveness of the vaccines in patients receiving immunosuppressive agents. For this reason, some countries have advised to use RNA vaccines in such a population to maximize the benefits of the vaccination.

Are there any special considerations when vaccinating people with AID who are taking immunosuppressants (e.g. Humira), IL-1 inhibitors (Kineret, Ilaris) and IL-6 (Actemra)?



There is no safety concern with regards to the vaccination of people living with autoinflammatory treated with immunomodulating or immunosuppressive treatments (no risk of infection or side effects).

The only concern is about the effectiveness of the vaccines in patients receiving immunosuppressive agents. For this reason, some countries have advised to use RNA vaccines in such a population to maximize the benefits of the vaccination.

The COVID-19 vaccines are recommended whatever the treatment.

Can the vaccine possibly trigger a flare for a patient who has been in remission?

Vaccines have been associated with flares of systemic autoinflammatory disorders (e.g., Marshall syndrome, not targeted in the ImmunAID project). Thus, this is possible, but not reported to date. For this reason, this should not be considered as a contraindication for the vaccination of such patients, COVID-19 being potentially largely more severe than a SAID flare. The question has to be asked to your usual doctor, who knows best your medical history.

Does the COVID vaccine have any effect/interaction with colchicine?

No specific study has been conducted to date, and there is no evidence for any interaction with colchicine or side effects in patients treated with colchicine. From a general point of view, colchicine is not known to be problematic with any vaccine.

What is the worst known adverse reaction someone has had to the vaccine?

The worst adverse reaction is anaphylactic shock syndrome. The persons at risk of anaphylaxis are people previously allergic to polysorbate, polyethylene-glycol impact or other vaccines. Another serious side effect is flu-like syndrome lasting for 3 or 4 days after immunization, leading to short-term impact on quality of life and sick leave.

If the reaction is related to an allergic phenomenon, it is advised to consult an allergologist before to receive the COVID vaccine.

Can the vaccine lessen its protective effects against amyloidosis?

No relation between the vaccine and amyloidosis.

Do FMF specialists advice immediate vaccination or should we expect more hindsight on the effects of vaccination on «healthy» populations?

A FMF patient well controlled by ongoing medication can be considered healthy. No specific recommendation for such patients, knowing that there is an urgent need to immunize the largest amount of people across the world to block the epidemics.

Are studies on the post-vaccination effects on a sample of AID patients in progress? No study has been conducted so far, but a EULAR study (COVIVAX) is ongoing for people with in-



flammatory conditions.

Is it true that the second dose may cause more symptoms? Are they noticing any AID related responses to the second shot?

There is no clear published data on this point. However, it appears that people who already experienced COVID-19 infection are more at risk of developing fever and flu-like syndrome after COVID vaccine, notably after the 2nd injection due to the presence of anti-COVID antibodies. This is usually not problematic and can reflect higher reactivity (and efficacy) against the virus.

Is the vaccination also recommended for AID patients with kidney transplant and diabetes?

Yes, the population of patients with organ transplant is considered to have the highest degree of priority for COVID vaccination.

How long does the immunity of the vaccine lasts?

This is currently under investigation. To date the answer is at least 6 months.

Does the vaccine prevent transmission of COVID-19?

The COVID vaccine trials already published did not report any data to assess this additional benefit of the vaccine.

However, two elements can be highlighted to answer the question indirectly:

- The transmission of COVID-19 is directly dependent on the quantity of virus in the body (viral load)
- The aim of the vaccine is to develop neutralizing antibodies against SARS-COV-2 to block its development and rapidly eliminate it. Thus, the vaccine will help in viral load reduction, and by this means is likely to reduce COVID-19 transmission (as it has been observed with many other vaccines).

We hope these answers can help you in staying safe! Take care of yourself!

