Académie nationale de Pharmacie

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Vaccination against SARS-CoV-2

While waiting for longer term responses, the National Academy of Pharmacy welcomes the current innovation in terms of vaccine strategies.

The National Academy of Pharmacy welcomes the efforts made by researchers to develop vaccines against SARS-CoV-2 as quickly as possible and thereby contribute to combating the Covid-19 epidemic as of 2021. In less than a year, a dozen candidate vaccines are already in phase III clinical trials, and even if most of them will probably never reach the final stage of marketing, the successive announcements made on the 9th and 16th of November by the German start-up BioNTech and the American laboratory Pfizer, as well as by the Moderna laboratory concerning their candidate vaccine are raising great hopes.

BEYOND THE PRESS HYPE?

➢The preliminary results seem to indicate efficacy rates of 90% and more, well above the levels of protection guaranteed by the viral vaccines currently on the market, with the exception of live vaccines. By way of comparison, the seasonal influenza vaccine has an efficacy of between 30% and 60%, depending on the year and the population vaccinated.

➢However, a press release is not enough. The results must be peer-reviewed and published scientifically to be validated. In view of the industry's statements, the two phase III trials seem, however, to have followed a rigorous methodology. The BioNTech/Pfizer trial was a double-blind, placebo-controlled trial with more than 43,000 participants (aged 16 to 85 years) and monitored by a committee of independent experts; the Moderna trial involved more than 30,000 volunteers.

A double scientific and technological revolution

These vaccines are a first in vaccination. Unlike conventional vaccines consisting of killed, attenuated viruses or proteins, these are modified messenger RNA vaccines encoding a protein from the SARS-CoV-2 spike. After injection, this messenger RNA will produce the viral protein in the body that will in turn trigger the immunological response and protection against further infection. The organism will therefore make its own vaccine after the injection of part of the

genetic code of the virus. These vaccines are easier to produce than traditional vaccines, which may partly explain their advance. It will still be several months before the safety of the vaccine can be assessed with certainty, but the messenger RNA remains in the body only temporarily and cannot be integrated into the human genome under any circumstances

A revolutionary vaccine technology. The other innovative aspect results from the encapsulation of the modified messenger RNA in lipid nanoparticles because it must be delivered intact into the immunocompetent cells. Naked RNA is, in fact, rapidly degraded in the organism and does not penetrate into cells. This approach can be considered biomimetic because the size of these nanovaccines is close to that of the virus.

Hopes ...but also reservations

➢It is too early to know how long the protection will last, it was evaluated between 7 and 15 days after vaccination, when immunity is theoretically at its peak.

➢ The efficacy of vaccine protection is not yet known by age group, especially for vulnerable people, who are more likely to develop a severe form of the disease.

➢ Moderate side effects and significant antibody production were observed in subjects aged 18 to 55 years included in the BioNTech/Pfizer Phase I/II clinical trial[i].

➢Generating vaccine immunity requires two injections, which may complicate the vaccination protocol with risks of a break in supplies to meet the demand.

➢The battle of the cold chain. The Moderna vaccine can be stored for one month without the use of "super-freezers", unlike the -80° required by BioNTech/Pfizer vaccine.

[i] Mulligan MJ et al, Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults, Nature, 589-593 (2020)