
FIP Holding Statement on interferon beta and vaccination for COVID-19 (July 2020)

An FIP Holding Statement is an initial statement about an issue or issues pending further evidence and about which FIP intends to make a further statement, in these cases, with further evidence. It is not a FIP Position Statement.

30 July 2020

Interferon beta

Trial medicine SNG001, delivered via an inhaler and containing interferon beta has been found to significantly reduce hospital patients with COVID-19 needing to be put on a ventilator. Inhaled SNG001 also reduced mortality.¹

A double-blind placebo-controlled trial involved 101 patients who had been admitted to hospital with COVID-19. Half were given SNG001 and the other half a placebo. SNG001 was given for up to 14 days, with post-treatment data collected on days 15 and 16 and patients monitored up to day 28. There were 3 deaths in the placebo group and no deaths in the SNG001 group.

The current FIP guidelines (published 15 July 2020) recommend against the use of interferon beta for the treatment of severely or critically ill patients with COVID-19 except in a clinical trial. Given the substantial morbidity and mortality associated with COVID-19, FIP welcomes these promising results. Sufficient evidence of efficacy and safety is awaited before SNG001 is a recommended treatment outside of a clinical trial. Peer review and publishing of the trial data are necessary next steps. FIP will then consider the published evidence and update its guidance accordingly.

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More than 140 candidate vaccines are being tracked by the World Health Organization. A total of 19 vaccines are currently in phase 1, 11 are in phase 2 and three are in phase 3 trials.²

An example of a trial progressing to phase 3 studies is the ChAdOx nCoV-19 vaccine against SARS-CoV-2 (an international collaboration).³ A preliminary report of the safety and immunogenicity of the ChAdOx nCoV-19 vaccine indicated that the vaccine had an acceptable safety profile and increased antibody responses in 1,077 participants. These results have supported large-scale evaluation of the vaccine in an ongoing phase 3 programme in South Africa and Brazil.

FIP welcomes the results of this trial and supports the need for a large phase 3 trial to generate the relevant efficacy and safety data. FIP agrees with the position of international regulators⁴ that vaccines should be assessed on a case by case basis (depending on how each vaccine is constructed and the totality of data available) and meet robust success criteria.

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References

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3. Folegatti PM, Ewer K J, Aley PK, et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. The Lancet. Published online July 20, 2020 DOI:[https://doi.org/10.1016/S0140-6736\(20\)31604-4](https://doi.org/10.1016/S0140-6736(20)31604-4)
4. Available at: www.icmra.info/drupal/news/22june2020/summary (Accessed 29 July 2020).