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| Name of Sponsor: IRCCS OSPEDALE SAN RAFFAELE | | Statement on discontinuation of the study |  |
| Investigational Product: Interferon-β-1a (IFNβ-1a) | | EudraCT No.: 2020-002458-25 | |
| | | Page: 1 | |
| Report Date: 28/03/2022 | Trial No.: INTERCOP | Dates of Trial: 02/11/2020 | |
| Title of Trial: | | Randomized, controlled, open label, phase 2 clinical trial of Interferon-β-1a (IFNβ-1a) in COVID-19 patients. | |
| Trial Sites: | | IRCCS Ospedale San Raffaele | |
| Publications: | | Pending review | |
| Clinical Phase: | | II | |
| Statement on discontinuation of the study: | | <p>An unplanned interim analysis was requested by the PI based on the negative results from the Solidarity Trial Consortium (Solidarity N Engl J Med. 2021 Feb 11;384:497-511) published in concomitance with the conduction of the present trial.</p> <p>The interim analysis was conducted with 56 patients recruited and 53 patients randomized. The aim of the interim analysis was to evaluate whether the primary outcome measure had any statistically significant result, or, in the absence of that, any positive tendency was present.</p> <p>Trial continuation or interruption would have been following established based on a simulation study, which included data from accrued patients and expected data from patients yet to be recruited.</p> <p>Based on the simulation study, attaining a statistically significant result with trial completion was highly improbable.</p> <p>Thus, the PI decided to prematurely terminate the trial for futility.</p> | |