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Interleukin-6 Inhibitors in Treating Severe COVID-19

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Interleukin-6 Inhibitors

As of March 27, 2020, the 7th edition of the Chinese Clinical Guidance for COVID-19 pneumonia diagnosis and treatment published by the China National Health Commission on March 4, 2020 included an interleukin (IL)-6 receptor inhibitor (a humanized anti-IL-6 receptor antibody) "tocilizumab" as an therapeutic option for severe COVID-19 patients, patients with extensive pulmonary lesions and IL-6 level elevation [1]. High IL-6 level is observed in COVID-19 patients for at least 2 weeks after disease onset. This IL-6 inhibitor demonstrated the positive outcomes in 21 severe COVID-19 patients with severe pulmonary inflammation.

There are several ongoing or planned studies for the US Food and Drug Administration (FDA)-approved IL-6 inhibitors in patients with COVID-19 as the following:

1. NCT04310228 (multicenter, open label, randomized control trial (3 arms)), favipiravir+tocilizumab, compared with favipiravir alone or tocilizumab alone, date of primary completion-May 2020);
2. NCT04306705 (retrospective cohort study (3 arms), tocilizumab with standard of care, compared with continuous renal replacement therapy with standard of care or standard of care alone, date of primary completion-May 2020);
3. NCT04322188 (observational, case-control study, siltuximab, compared with standard of care, date of primary completion-May 2020);
4. NCT04317092 (single-arm, multicenter, phase II, observational cohort study, tocilizumab, no comparator, date of primary completion-December 2020);
5. NCT04321993 (open label, phase II, non-randomized study, lopinavir/ritonavir, hydroxychloroquine sulphate, baricitinib, sarilumab, no comparator, date of primary completion-February 2021);
6. NCT04315298 (double blind, phase II/III, randomized control trial (3 arms), high dose sarilumab, low dose sarilumab, compared with placebo, date of primary completion-March 2021);
7. NCT04320615 (multicenter, open label, randomized control trial (4 arms), intravenous tocilizumab, subcutaneous tocilizumab, subcutaneous sarilumab, compared with standard medical care, date of primary completion-June 2021);
8. NCT04320615 (multicenter, double blind, phase III, randomized control trial, tocilizumab, compared with placebo, date of primary completion-August 2021) [1].

A trial "COVACTA" on tocilizumab will recruit about 330 COVID-19 patients around the world, with expected start date sometime in early April 2020 [2]. A drug company in the US has announced the initiation of a randomized controlled clinical trial of sarilumab, an antibody to the interleukin (IL)-6 receptor, to evaluate whether the modification of the lung inflammatory response by therapeutic intervention provides the benefit to COVID-19-infected patients [3].

Although none of the IL-6 inhibitors are mentioned by the World Health Organization (WHO), the Society of Critical Care Medicine, and the European Society of Intensive Care Medicine, a number of professional bodies have included tocilizumab as a therapeutic option for selected sever COVID-19 patients as the following:

1. Chinese Clinical Guidance for COVID-19;
2. The Italian Society of Infectious Diseases and Tropical Diseases COVID-19 Guidelines;
3. Michigan Medicine (University of Michigan); and
4. The Society for Immunotherapy of Cancer.

Several other US FDA-approved IL-6 inhibitors currently are in trials: ALX-0061, ARGX-109, BMS945429(ALD518), clazakizumab, CPSI-2364, elsilimomab, FE301, FM101, olokizumab (CDP6038), olokizumab, sirukumab (CNTO136), and sirukumab. Other promising drugs includes Janus kinase (JAK) inhibitors (baricitinib, inositol-requiring transmembrane kinase/endoribonuclease (IRE1α)), tylophorinebased compounds, and tracolimus [4].

In conclusion, clinicians should wait for the results of several ongoing clinical trials to exactly define the role of tocilizumab, a safe and efficacious IL-6 inhibitor in preliminary studies prior to routine clinical use.

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