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Tocilizumab in COVID-19: a study of adverse drug events reported in the WHO database

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Abstract

Background: Elevated inflammatory cytokines in Coronavirus disease 2019 (COVID-19) affect the lungs leading to pneumonitis with a poor prognosis. Tocilizumab, a type of humanized monoclonal antibody antagonizing interleukin-6 receptors, is currently utilized to treat COVID-19. The present study reviews tocilizumab adverse drug events (ADEs) reported in the World Health Organization (WHO) pharmacovigilance database. Research design and methods: All suspected ADEs associated with tocilizumab between April to August 2020 were analyzed based on COVID-19 patients' demographic and clinical variables, and severity of involvement of organ system. Results: A total of 1005 ADEs were reported among 513 recipients. The majority of the ADEs (46.26%) were reported from 18–64 years, were males and reported spontaneously. Around 80%, 20%, and 64% were serious, fatal, and administered intravenously, respectively. 'Injury, Poisoning, and Procedural Complications' remain as highest (35%) among categorized ADEs. Neutropenia, hypofibrinogenemia were common hematological ADEs. The above 64 years was found to have significantly lower odds than of below 45 years. In comparison, those in the European Region have substantially higher odds compared to the Region of Americas. Conclusion: Neutropenia, superinfections, reactivation of latent infections, hepatitis, and cardiac abnormalities were common ADEs observed that necessitate proper monitoring and reporting. © 2021 Informa UK Limited, trading as Taylor & Francis Group.

Author Keywords

adverse drug event; COVID-19; interleukin-6; monoclonal antibody; pharmacovigilance; Tocilizumab; WHO

Index Keywords

monoclonal antibody, tocilizumab; adolescent, adult, age distribution, aged, drug surveillance program, drug therapy, factual database, female, human, male, middle aged, sex ratio, World Health Organization, young adult; Adolescent, Adult, Adverse Drug Reaction Reporting Systems, Age Distribution, Aged, Antibodies, Monoclonal, Humanized, COVID-19, Databases, Factual, Female, Humans, Male, Middle Aged, Pharmacovigilance, Sex Distribution, World Health Organization, Young Adult

Chemicals/CAS

tocilizumab, 375823-41-9; Antibodies, Monoclonal, Humanized; tocilizumab

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