Inserm

La science pour la santé
From science to health

Paris, 20 September 2021

Press information

Remdesivir Ineffective in Patients Hospitalized With COVID-19 and the DisCoVeRy Trial Continues with a New Antiviral

The Discovery clinical trial was initially launched in France by Inserm in March 2020, to evaluate several possible treatments for COVID-19. Its European expansion was made possible by the EU-RESPONSE[1] project, funded by the European Commission. Interim analysis of the trial data had led to the recommendation to suspend the recruitment of remdesivir group patients for futility – that is to say due to the very low likelihood of this treatment showing a benefit, even if inclusions were continued. In an article published this week in *The Lancet Infectious Diseases*, the final scientific analysis shows no improvement in patients hospitalized with COVID-19 presenting respiratory symptoms requiring oxygen and treated with remdesivir.

Data from 832 patients hospitalized between March 2020 and January 2021, recruited in 5 European countries (418 patients receiving standard of care and 414 additionally receiving remdesivir), were analyzed. The analysis has shown no difference between the two groups in patient clinical status 15 and 29 days after receipt of the first remdesivir dose, in time to discharge from hospital, and in death rate on Day 28. There was also no demonstrated difference between the groups in terms of speed of elimination of the virus at nasopharyngeal level. Severe side effects were distributed similarly between the two groups. These data support those of the Solidarity trial conducted by the WHO, in particular by providing results on a larger number of endpoints.

In order to continue to analyze the efficacy of the treatments evaluated on a larger number of patients, the data collected during Discovery are being used to perform meta-analyses. The data used to analyze the efficacy of remdesivir are therefore being shared, within the framework of the EU-RESPONSE project, with those of other major international studies, to clarify the results on a larger scale.

"18 months after the launch of Discovery, it can be concluded that 4 different molecules offer no therapeutic benefit in patients hospitalized for COVID-19. This huge undertaking has made it possible to further knowledge on sound scientific foundations. Although, like everyone else, we would have preferred to prove the efficacy of a treatment, we are continuing our research with an approach that specifically targets the virus," explains Florence Ader, principal investigator of the trial.

With the epidemic still ongoing, it is essential to pursue research efforts to find a treatment for COVID-19 that is effective against the virus and its new variants. The DisCoVeRy trial is thus continuing in 80 hospitals across 14 European countries to assess the efficacy of a combination of two monoclonal antibodies targeting SARS-CoV-2 and currently effective against its variants. This treatment, developed by AstraZeneca, has appeared effective in a recent preventive treatment trial in which it reduced by 77% the risk of developing symptomatic COVID, thereby reducing hospitalization and potentially harmful outcomes. In addition, another trial has shown decreased mortality in patients hospitalized with COVID-19 who did not develop natural antibodies and who received treatment with monoclonal antibodies.[2] Monoclonal antibody treatments are therefore the first antivirals to show efficacy in the prevention and treatment of COVID-19 in non-immunized patients. Evaluating the efficacy of these monoclonal antibodies in hospitalized patients is therefore important when it comes to identifying curative treatments that reduce mortality and the number of severe forms of the disease.

[1] https://cordis.europa.eu/project/id/101015736

In addition, within the framework of EU-RESPONSE – now the European platform for clinical trials in response to emerging infectious diseases – the SolidACT trial has started in three European countries with the objective of evaluating baricitinib in patients hospitalized for severe forms of COVID-19.

Source

Remdesivir plus standard of care versus standard of care alone for the treatment of patients admitted to hospital with COVID-19 (DisCoVeRy): a phase 3, randomised, controlled, open-label trial

Florence Ader, Maude Bouscambert-Duchamp, Maya Hites, Nathan Peiffer-Smadja, Julien Poissy, Drifa Belhadi, Alpha Diallo, Minh-Patrick Lê, Gilles Peytavin, Thérèse Staub, Richard Greil, Jérémie Guedj, Jose-Artur Paiva, Dominique Costagliola, Yazdan Yazdanpanah, Charles Burdet*, France Mentré*, and the DisCoVeRy Study Group

Département des Maladies Infectieuses et Tropicales, Hôpital de la Croix-Rousse, Hospices Civils de Lyon, Lyon, France (Prof F Ader MD); Legiopath, Université Claude Bernard Lyon 1, CIRI, INSERM U1111, CNRS UMR5308, ENS Lyon, Lyon, France (Prof F Ader);
Laboratoire de Virologie, Institut des Agents Infectieux de Lyon, Centre National de Référence des Virus Respiratoires France Sud, Hospices Civils de Lyon, Lyon, France (M Bouscambert-Duchamp PharmD);
Cliniques Universitaires de Bruxelles— Hôpital Érasme, Université Libre de Bruxelles, Clinique des Maladies Infectieuses, Brussels, Belgium (Prof M Hites MD); Université de Paris, IAME, INSERM, Paris, France (N Peiffer-Smadja MD, D Belhadi MSc, G Peytavin PharmD, J Guedj PhD, Prof Y Yazdanpanah MD, C Burdet MD, Prof F Mentré MD);
Service de Maladies Infectieuses et Tropicales, Hôpital Bichat, AP-HP, Paris, France (N Peiffer-Smadja, Prof Y Yazdanpanah);
National Institute for Health Research, Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance, Imperial College London, London, UK (N Peiffer-Smadja);
Unité de Glycobiologie Structurale et Fonctionnelle, Université de Lille, Inserm U1285, CNRS, UMR 8576, Lille, France (Prof J Poissy MD); Pôle de Réanimation, CHU Lille, Lille, France (Prof J Poissy);
Département d'Épidémiologie, Biostatistique et Recherche Clinique, Hôpital Bichat, AP-HP, Paris, France (D Belhadi, C Burdet, Prof F Mentré);
Pharmacovigilance, ANRS-MIE, Paris, France (A Diallo MD);
Laboratoire de PharmacologieToxicologie, AP-HP, Hôpital Bichat Claude Bernard, Paris, France (M-P Lê PharmD, G Peytavin);
Université de Paris, INSERM, UMRS 1144, Paris, France (M-P Lê);
Service des Maladies Infectieuses, Centre Hospitalier de Luxembourg, Luxembourg, Luxembourg (Prof T Staud MD);
Department of Internal Medicine III with Haematology, Medical Oncology, Haemostaseology, Infectiology and Rheumatology, Oncologic Center, Salzburg Cancer Research Institute—Laboratory for Immunological and Molecular Cancer Research, Paracelsus Medical University Salzburg, Salzburg, Austria (Prof R Greil MD); Cancer Cluster Salzburg, Salzburg, Austria (Prof R Greil);
AGMT, Salzburg, Austria (Prof R Greil);
Emergency and Intensive Care Department,Centro Hospitalar São João, Porto, Portugal (Prof J-A Paiva MD); Faculty of Medicine, Universidade do Porto, Porto, Portugal (Prof J-A Paiva);
Sorbonne Université, Inserm, Institut Pierre-Louis d'Épidémiologie et de Santé Publique, Paris, France (D Costagliola PhD)

The lancet infectious diseases

https://doi.org/10.1016/S1473-3099(21)00485-0

Press contact

Inserm
presse@inserm.fr