Sotrovimab

Approved indication: COVID-19

Xevudy (GlaxoSmithKline)
vials containing 500 mg/8mL concentrate for dilution

While vaccines are essential for controlling the pandemic caused by SARS-CoV-2, there is a need to identify the best treatment for patients who become infected and develop COVID-19. Sotrovimab is a monoclonal antibody that has been given provisional approval for patients, over 12 years of age, who do not require oxygen therapy, but have an increased risk of hospitalisation or death.

Sotrovimab has been genetically engineered to bind to the spike protein of SARS-CoV-2. Animal studies show that this binding neutralises the virus. The genetic engineering extends the half-life of the monoclonal antibody. This gives sotrovimab a median elimination half-life of about 49 days. The recommended regimen is therefore a single intravenous infusion of 500 mg. Sotrovimab must be diluted before being infused over 30 minutes.

When sotrovimab was provisionally approved the results of a clinical trial (COMET-ICE) had not been published in a peer-reviewed journal. This trial randomised unvaccinated patients with confirmed infection who were at high risk of complications. Risk factors included asthma, chronic obstructive pulmonary disease, chronic kidney disease and diabetes. An interim analysis reported that COVID-19 had progressed in 3/291 patients infused with sotrovimab and 21/292 given a placebo. The five patients who subsequently needed intensive care were all from the placebo group.[1]

The data considered by the Therapeutic Goods Administration included 528 patients given sotrovimab and 529 given placebo. Approximately 20% of these patients were over 65 years old. The infusion was given within five days of the onset of symptoms. A large difference emerged between the two groups and the trial stopped recruiting new patients. By day 29, 6% of the patients in the placebo group had died or been admitted to hospital compared with 1% of the sotrovimab group. Two people in the placebo group died.

During the trial the rate of adverse events was similar for sotrovimab and placebo (22% vs 23%). Common complaints were diarrhoea, nausea and headache. Infusing an antibody also has the potential to cause hypersensitivity reactions.

Due to its rapid approval, the data on sotrovimab are limited. Further research will be needed to know if it is effective for young children, pregnant women or the immunosuppressed. The effect of vaccination on the safety and efficacy of sotrovimab is also unknown. It is uncertain which at-risk patients should be given sotrovimab. Approximately 16 people need to be treated to prevent one hospitalisation or death, so the logistics of giving everyone at risk an infusion may exceed the available resources and the supply of the drug. There is also the concern that antiviral resistance could develop.

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REFERENCE

1. Gupta A, Gonzalez-Rojas Y, Juarez E, Casal MC, Moya J, Falci DR, et al; the COMET-ICE Investigators. Early Covid-19 treatment with SARS-CoV-2 neutralizing antibody sotrovimab. MedRxiv. Preprint posted May 28, 2021 [cited 2021 Sep 27]. https://doi.org/10.1101/2021.05.27.21257096

The Transparency Score is explained in New drugs: transparency, Vol 37 No 1, Aust Prescr 2014;37:27.

At the time the comment was prepared, information about this drug was available on the websites of the Food and Drug Administration in the USA, the European Medicines Agency and the Therapeutic Goods Administration.

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