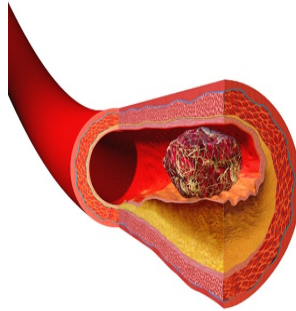


Alteplase Under Review



The UK Medicines and Healthcare Products Regulatory Agency (MHRA) is currently reviewing the safety of alteplase, a clot-busting drug. The drug is to be reviewed for the treatment of strokes. The regulatory agency believes that the benefits of alteplase outweigh its risks but because there is a chance that some previous assessments may have been flawed, the agency is revisiting the evidence. This review could possibly have huge implications for patient safety.

Boehringer Ingelheim is the manufacturer of the drug and stands by its safety. The company strongly believes that its drug is an emergency clot-busting treatment for patients who have just suffered a stroke. The drug has the potential to increase the survival rate of patients and to allow them to lead independent lives.

A stroke is a medical emergency. In the UK, there is one stroke every five minutes. The majority of strokes are caused by a clot blocking the flow of blood to the brain. Patients are often prescribed alteplase to break down and disperse the clot.

It is believed that there might be an increased risk of dangerous bleeding in the brain with alteplase. While regulators had previously concluded that this risk is outweighed by the benefits of the drug, some experts still disagree. According to Dr. Roger Shinton, a stroke specialist, "My concerns using alteplase for stroke have always been that the risks of this drug are quite considerable, particularly with bleeding into the brain. The question is, do the benefits justify that risk? And I am not myself convinced that they do." He revealed that this concern was shared by many other stroke specialists.

Although MHRA has recently examined this issue and has concluded that the drug is favourable because of its benefits, it has now confirmed that an expert working group will once again gather evidence and review the drug. Findings of this inquiry are expected to be reported early next year.

Jon Barrick, the Chief Executive of the Stroke Association, considers alteplase an important component of the treatment of thrombolysis and believes that it is part of the great progress being made in stroke treatment. He says that there is no treatment without risks and the drug is being used based on the recommendation of the National Institute for Health and Care Excellence (NICE). He also conveyed that patients treated for thrombolysis are likely to have a good outcome and that more people are now surviving stroke and leading independent lives.

This announcement by MHRA has been welcomed by consultants, and several specialists support the investigation since it could result in huge implications for both patient safety and the treatment of acute stroke.

Source: BBC Health
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Published on : Mon, 25 Aug 2014