

People can regain remission after relapse with rituximab plus steroids



Rituximab plus steroids are useful for putting people back into remission after a relapse of their AAV.

INTRODUCTION

ANCA-associated vasculitis (shortened to AAV), is a rare group of diseases of the immune system. These diseases are linked to a type of autoantibody called ANCA. An antibody is a protein that the normal healthy immune system makes to attack foreign substances in the body, such as viruses or bacteria. In people with AAV the body makes antibodies that attack its own tissues – these are called autoantibodies. In AAV, the ANCA autoantibodies cause damage to small blood vessels. Any part of the body can be affected, but AAV most often affects a person's kidneys, lungs, joints, nerves, and may cause bleeding in their nose and ears. AAV is very severe, and can be life-threatening if left untreated.

Azathioprine has been used for many years to keep AAV in remission. Remission means that the disease is under control, and there are no signs of symptoms of active disease. Rituximab is another type of drug that is used in other autoimmune diseases, but it could also be useful in people with AAV. Rituximab is one of a group of medicines called biologics (sometimes also called bDMARDs). It works by targeting B cells, a type of white blood cell, which produce ANCA antibodies.

WHAT DID THE AUTHORS HOPE TO FIND?

The authors wanted to see if rituximab can help people get into remission after a relapse (worsening) of their disease.

WHO WAS STUDIED?

The study included 188 people with AAV at 25 treatment centres around the world. Everyone entering the study was experiencing a relapse of their disease.

HOW WAS THE STUDY CONDUCTED?

This was an initial induction study as part of a larger trial called RITAZAREM. Overall, the trial has three parts. The first (the induction phase) aims to get people to remission with rituximab. The second part is a maintenance phase to test rituximab against azathioprine to see which keeps people in remission better. The third part is a follow-up phase to see how well people do when all treatment is discontinued.

In the induction phase, everybody was given rituximab plus steroid medicines to treat their disease relapse, and to try to get them to remission. This part of the study lasted for 4 months. The main trial (part 2) is a randomised, controlled trial to see whether rituximab is better than azathioprine for maintaining remission that has been achieved with an initial treatment of rituximab plus steroids. Randomised trials are a strong way to test treatments because they allocate people to groups by chance and allow comparisons to be made.

This report looks only at the observations made during the first induction phase.

WHAT WERE THE MAIN FINDINGS OF THE STUDY?

The main finding was that rituximab used together with a steroid worked very well. After 4 months 90% of people had achieved remission. The safety results were similar to those seen before in other studies.

ARE THESE FINDINGS NEW?

No. However, although these findings are not new, they are still important. This is the largest group of people with relapsing disease to receive rituximab in a clinical trial. This means the findings are useful and add weight to previous findings.

WHAT ARE THE LIMITATIONS OF THE STUDY?

A limitation of the study is that there was no control group in this initial part to compare against because everyone in this part of the study received rituximab and steroids. However, these people will now move into the next part of the study, where they will be either continue taking rituximab, or switch to azathioprine.

WHAT DO THE AUTHORS PLAN ON DOING WITH THIS INFORMATION?

The next part of the trial will give us more information about whether people do better with rituximab or azathioprine to keep them in remission. The next phase of results will be published and shared.

WHAT DOES THIS MEAN FOR ME?

If you have AAV, you may be offered rituximab and steroids to treat relapses. In the future, there may be new treatment options to help keep you in remission.

Speak to your doctor if you have any questions or concerns about your disease or its treatment.

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