

Switch to baricitinib delivers results with no need for washout



Switching from adalimumab to baricitinib delivers improvements in disease control, physical function and pain within 12 weeks, without additional side effects

INTRODUCTION

Rheumatoid arthritis is a chronic inflammatory disease that affects a person's joints, causing pain and disability. It can also affect internal organs. Rheumatoid arthritis is more common in older people and it affects women more frequently than men.

There are a lot of treatments available for rheumatoid arthritis. People often try different treatments before they find the one that is right for them. When people move from one treatment to another it is called 'switching'. People might switch treatments because they have side effects, or because a treatment doesn't work very well for them, or stops working over time. In some countries, treatment might be switched even if it is working well, mostly for cost reasons.

Adalimumab is a TNF inhibitor. TNF inhibitors belong to a group of medicines called biologic disease-modifying antirheumatic drugs, or biologics (abbreviated as bDMARDs). These drugs work by blocking TNF, a molecule that causes inflammation. Adalimumab is given as an injection. Baricitinib is a newer drug from a group of medicines called the JAK inhibitors. These also work by reducing inflammation, but they do it in a different way to other drugs by targeting special pathways inside cells. Baricitinib is a pill that is taken by mouth.

WHAT DID THE AUTHORS HOPE TO FIND?

The authors wanted to find out if baricitinib would provide good symptom relief for people who were not getting a good response taking adalimumab. They also wanted to see whether people who responded well to adalimumab but were switched to baricitinib would continue to do well without any side effects.

WHO WAS STUDIED?

The study looked at people with rheumatoid arthritis who had not had a good clinical response to a drug called methotrexate. Everyone was over the age of 18 and nobody had taken a biologic medicine before.

HOW WAS THE STUDY CONDUCTED?

This was a blinded, randomised control trial, which means that patients were assigned by chance to the treatment groups and – at the start of the whole trial – were not aware which treatment they were receiving. Using chance in this way means that the groups will be similar and will allow the treatment under investigation to be compared objectively. The main study lasted for 52 weeks, and then some people went into an extension period.

The study was designed so that people could switch to 4 mg baricitinib at three different points.

The first time people could switch was at 16 weeks if they were not responding to the treatment they had been randomised to at the start (either placebo, adalimumab, or baricitinib 4 mg). The second time was at 24 weeks, when everyone randomised to placebo at the start was switched to baricitinib. The third time was at 52 weeks, when everyone who completed the study on adalimumab was switched to baricitinib. There was no treatment gap when people switched treatment (sometimes called a washout period) – they went straight from one drug to the other. The study then measured how well people were doing 12 weeks after they switched.

WHAT WERE THE MAIN FINDINGS OF THE STUDY?

Many people who were switched from adalimumab or baricitinib because they were not working very well were doing much better after 12 weeks taking baricitinib 4 mg. Some people who had been doing well on adalimumab but who were switched to baricitinib after 52 weeks also showed signs of improvement 12 weeks after the switch. There was no increase in side effects in the people switching treatments.

ARE THESE FINDINGS NEW?

These findings are new in several ways. This is the first time that a study has shown that people who do not do well on adalimumab can benefit from a switch to baricitinib. It is also the first study to show that people who are responding well to adalimumab might do even better if they are switched to baricitinib.

Finally, an important new finding was that there is no need to leave a gap before switching people to baricitinib.

WHAT ARE THE LIMITATIONS OF THE STUDY?

Because of the way the study was designed, some people knew which treatment they were taking once they were switched from the original treatments that didn't work for them (but were still blinded to their original, randomised treatment). This might introduce something called an 'expectation bias'; this can, for example, be seen in patients who did not respond to baricitinib and then were given again baricitinib and did better. Also, the study took place over a relatively short period of time. Measuring how well people do in the long term after switching treatments would provide more important information.

WHAT DO THE AUTHORS PLAN ON DOING WITH THIS INFORMATION?

The study carried on to measure how well baricitinib was working 48 weeks after the switch. This information has been shared with other doctors at a medical conference.

WHAT DOES THIS MEAN FOR ME?

If you have rheumatoid arthritis, and are taking adalimumab, these results suggest that there are options to switch to newer treatments if adalimumab doesn't work for you, or if it stops working over time. They also suggest that if you need to switch from adalimumab for other reasons – perhaps because you no longer want to have injections, or if you get side effects – that you might get an extra benefit from taking baricitinib 4 mg pills every day instead. Importantly, these results also mean that you might not need to leave a gap between your old and new treatments.

If you have any concerns about your disease or its treatment, you should talk to your doctor.

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Date prepared: June 2019

Summary based on research article published on: 30 April 2019

From: Tanaka Y, *et al.* Clinical outcomes in patients switched from adalimumab to baricitinib due to non-response and/or study design: phase III data in patients with rheumatoid arthritis. *Ann Rheum Dis* 2019;78:890–898. doi:10.1136/annrheumdis-2018-214529

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