

## RA-BUILD shows clinical improvement with baricitinib



Baricitinib gives clinical improvement and inhibits joint damage in people with rheumatoid arthritis and an inadequate response or intolerance to csDMARDs

### INTRODUCTION

Rheumatoid arthritis is a chronic inflammatory disease that affects a person's joints, causing pain and disability. It is more common in older people, and affects both men and women.

Baricitinib is a new drug for rheumatoid arthritis called a Janus kinase (JAK) inhibitor. It works in a different way to other drugs by targeting a specific pathway inside cells, helping to reduce inflammation. JAK inhibitors are targeted synthetic molecules (sometimes called tsDMARDs), which means they can be given as oral pills.

### WHAT DID THE AUTHORS HOPE TO FIND?

Several trials of baricitinib have already been done in people with rheumatoid arthritis. This study focused on people suffering from rheumatoid arthritis despite taking conventional synthetic disease-modifying antirheumatic drugs (also called csDMARDs), such as methotrexate.

### WHO WAS STUDIED?

The study looked at 684 people with rheumatoid arthritis from 182 clinics in 22 countries around the world. None of the people had taken a biologic drug (also called a biologic or bDMARD) before, and all had reported an inadequate response or intolerance to one or more csDMARDs.

### HOW WAS THE STUDY CONDUCTED?

The RA-BUILD study was a randomised, double-blind trial, which means that patients were assigned by chance to one of three treatment groups to receive once-daily pills containing either placebo (dummy drug), baricitinib 2 mg, or baricitinib 4 mg. Using chance in this way means that the groups are similar and allows the treatments to be compared objectively. The study lasted for 6 months. During this time neither the patients nor their doctors knew which group they were in.

### WHAT WERE THE MAIN FINDINGS?

The study found that both doses of baricitinib 2 and 4 mg improved people's symptoms of rheumatoid arthritis, including pain, fatigue, and functional disability. Baricitinib also improved the number of swollen joints, and reduced the levels of biological markers of inflammation in people's blood. For all these measures, the improvement over placebo was similar between the two different doses of baricitinib. Importantly, baricitinib treatment was effective no matter what other csDMARD people were using.

The authors also collected X-rays of people's hands and the feet before treatment, and after 24 and 48 weeks in the study. The X-rays were used to see whether people developed any new structural damage in their joints over the study period. These X-rays showed that people taking baricitinib had less progression of structural damage than people taking placebo. The results also suggested that the 4 mg dose was better than the 2 mg one for slowing down joint damage.

Side effects were similar among groups. One patient developed tuberculosis while taking baricitinib 4 mg, and one patient developed non-melanoma skin cancer, also while taking baricitinib 4 mg. Two people taking placebo died, and three had a major cardiovascular event.

### ARE THESE FINDINGS NEW?

RA-BUILD is part of a development programme which includes four global studies evaluating people in different stages of their disease.

### ARE THERE ANY LIMITATIONS?

Limitations of this study include the relatively short time (6 months). This means that it is not possible to draw definite conclusions about how baricitinib can be used. Also, the study included two doses of baricitinib, but was not designed to be able to compare them for any statistically significant differences.

Finally, there was a relatively high placebo response seen in this study, but the authors are confident that it is consistent with what is seen in other modern trials of drugs in people with rheumatoid arthritis.

### WHAT DO THE AUTHORS PLAN ON DOING WITH THIS INFORMATION?

These results together with other studies will support the development of baricitinib.

### WHAT DOES THIS MEAN FOR ME?

Baricitinib is not currently approved for use in rheumatoid arthritis, which means that you cannot be prescribed it yet unless you are in a clinical trial. However, the results highlighted in this article provide important information about the efficacy and safety of baricitinib. This information will be needed for any potential approval of the drug as a treatment option, and it may be available for you to try in the near future.

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