

## Endpoint not met, but golimumab delivers improvement in JIA



Golimumab results in rapid improvement in children with active polyarticular JIA

### INTRODUCTION

Juvenile idiopathic arthritis, commonly referred to as JIA, includes most types of arthritis seen in children before the age of 16. JIA is an umbrella term for a group of inflammatory arthritis conditions with unknown cause which begin in childhood. JIA causes pain, swelling and stiffness in one or more joints, as well as other symptoms like tiredness. Polyarticular JIA is a JIA subgroup that involves many joints.

JIA and rheumatoid arthritis are often treated with methotrexate first, but some people require treatment with medicines known as biologics. Biologics work by damping down the immune system, and therefore reducing the inflammation. Golimumab is a biologic medicine that has been approved to treat adults with rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis.

### WHAT DID THE AUTHORS HOPE TO FIND?

The authors wanted to see if injections of golimumab plus methotrexate would reduce the signs and symptoms of polyarticular JIA and also if continuing golimumab plus methotrexate would reduce the number of flares more than continuing treatment with methotrexate on its own in children for whom methotrexate treatment had not worked.

### WHO WAS STUDIED?

This study called GO-KIDS included 173 children aged 2–17 years who had been diagnosed with subtypes of JIA that involved multiple joints and no systemic features, such as fever. Everyone had active disease (at least 5 inflamed joints from JIA) despite having received methotrexate for at least 3 months.

### HOW WAS THE STUDY CONDUCTED?

In Part 1 (weeks 0 to 16), everyone received an injection of golimumab once every 4 weeks. At week 16, the children could enter Part 2 of the trial if they had at least a 30% improvement in the JIA American College of Rheumatology response criteria (JIA ACR30 response). In Part 2 (weeks 16–48), children were assigned by chance (randomly) to either stop golimumab treatment and switch to placebo (dummy drug) or continue golimumab treatment. In this second part, neither the children nor the healthcare professionals looking after them knew which treatment they were taking. Throughout the trial everyone continued to take methotrexate.

### WHAT WERE THE MAIN FINDINGS OF THE STUDY?

In Part 1, nearly 90% of children taking golimumab plus methotrexate had a 30% improvement in their condition (JIA ACR30 response) and 34% achieved inactive disease. The number of children who had a flare during Part 2 was similar for placebo and golimumab, which means that the trial did not meet its primary goal of golimumab being more effective than placebo, and because of this the third part that had been planned was cancelled. Before it was cancelled, 145 children continued in Part 3. At the time of the cancellation (160 weeks) there was no difference in the number of children who had achieved remission in the two groups.

The safety results were consistent with those from earlier studies of golimumab in adults with rheumatoid arthritis.

### ARE THESE FINDINGS NEW?

Golimumab has been studied before in adults with rheumatoid arthritis and other conditions, but this study was the first of its kind in JIA.

### WHAT ARE THE LIMITATIONS OF THE STUDY?

A key limitation of this study is the design. This kind of study design (called a withdrawal study) has been used before, and was introduced in JIA for ethical reasons to limit how long children receive a placebo for. However, biologic medicines can have long-standing effects and delay flares, which may explain the similar numbers of flares between children who received the active medicine and those who received the placebo in this study. Blood tests showed that the children who took part in the study had very low levels of inflammation. This may also have contributed to the results seen in Part 2.

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

Based on the improvement of signs and symptoms of JIA in Part 1 of this study, golimumab injections can be considered for treating children with moderate-to-severe JIA who have not had a good response to methotrexate on its own.

### WHAT DOES THIS MEAN FOR ME?

If you have JIA, or if you are looking after a child with JIA, there may be new treatment options available to you. If you are interested in finding out more, you should speak to your doctor.

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