NOVARTIS

Secukinumab effect in two types of arthritis seen in children and adolescents at two years

Full abstract title: Efficacy and Safety of Secukinumab in Enthesitis-related Arthritis and Juvenile Psoriatic Arthritis: Primary Results from a Randomised, Double-blind, Placebo-controlled, Treatment Withdrawal, Phase 3 Study (JUNIPERA)

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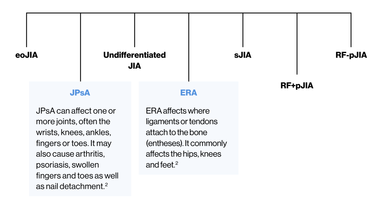
Please note that this summary only contains information from the full EULAR 2021 scientific abstract and selected supporting references. The results of this study may not reflect those of other studies. This summary is not intended to provide medical advice.

Why was this study done?

To investigate if secukinumab is an effective and safe treatment for juvenile psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA), two subtypes of juvenile idiopathic arthritis (JIA).

JIA is the most common type of arthritis in children and teenagers, beginning before the age of 16.[1] Symptoms of JIA can begin from as young as two years[1] and gradually worsen over time. All types of JIA can dramatically impact a child's life, causing pain, tenderness and stiffness in joints all over the body.[2] There are seven subtypes of JIA.*[1] This study focused on two types: JPsA and ERA.



JPsA

JPsA can affect one or more joints, often the wrists, knees, ankles, fingers or toes. It may also cause arthritis, psoriasis, swollen fingers and toes as well as nail detachment.[2]

ERA

ERA affects where ligaments or tendons attach to the bone (entheses). It commonly affects the hips, knees and feet.[2]

*According to ILAR, International League of Associations for Rheumatology
eoJIA, *extended oligo-articular juvenile idiopathic arthritis*; **RF+pJIA**, *rheumatoid factor-positive polyarticular juvenile idiopathic arthritis*; **RF-pJIA**, *rheumatoid factor-negative polyarticular juvenile idiopathic arthritis*; **sJIA**, *systemic idiopathic arthritis*.

JIA is an autoimmune disease,[2] meaning that the body's immune system is overactive, incorrectly attacking normal cells and causing unwanted inflammation. Inflammation can be good (eg, in fighting infection), but it can also become a problem if it occurs more than needed or without a good reason.

In JIA, the overactive immune system causes joints to become swollen and painful, as inflammation kicks in, and cartilage (the tissue between joints that helps bones slide smoothly against each other) is gradually destroyed.[2]

Idiopathic means that the disease has no known cause. It is thought that certain genes inherited from your parents may be activated by a virus, bacteria or other factors. There is no evidence that external factors such as allergies, toxins in the environment or food can cause the disease.[2]

JIA is the most common childhood rheumatic disease,[1] affecting approximately 2 million children worldwide.[3] The subtypes of JPsA and ERA each account for up to 11% of total JIA cases.[1]

Secukinumab is a type of medication called a biologic.

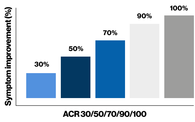
It works to reduce inflammation by blocking one of the molecules that causes inflammation to occur.[4] Therefore, it could help relieve the symptoms of JIA.

What did this study look at?

The study looked at the effect of secukinumab on the symptoms of two subtypes of JIA: JPsA and ERA.

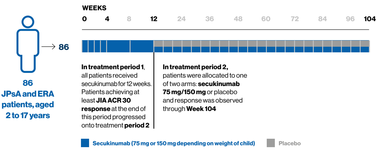
To observe the effect secukinumab had on joint symptoms, the time it took for joint symptoms to worsen (known as time to flare†) was measured between three months (12 weeks) and two years (104 weeks) of secukinumab treatment.

To check if any improvement was because of secukinumab, results were compared with the time to flare in patients when given a 'dummy' injection containing no active ingredient, called a placebo.



The study also measured how much secukinumab improved the severity of joint symptoms. To do this, a specific method was used to calculate the amount of improvement seen in joint pain, mobility and stiffness. This was referred to as JIA ACR 30/50/70/90/100, meaning a 30, 50, 70, 90 or 100% improvement in symptoms.

Design of the study



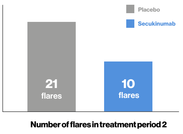
What did this study find?

At three months (Week 12):

9 in 10 children had achieved a 30% improvement in joint symptoms with secukinumab treatment (JIA ACR 30 response) – these children progressed to a second period of treatment in the study

At two years (Week 104):

For both JPsA and ERA patients who continued to be treated with secukinumab to two years, it was shown that it took significantly longer for their joint symptoms to get worse (time to flare) compared with those given placebo, or a 'dummy' treatment containing no active ingredient, with a 72% reduction in risk of flare



Number of flares in treatment period 2

JIA ACR 30 response
9 in 10 children in the secukinumab group had achieved a 30% improvement in joint symptoms with secukinumab treatment compared with **6 in 10 children** in the placebo group

JIA ACR 50 response
8 in 10 children in the secukinumab group had achieved a 50% improvement in joint symptoms with secukinumab treatment compared with **6 in 10 children** in the placebo group

JIA ACR 70 response
7 in 10 children in the secukinumab group had achieved a 70% improvement in joint symptoms with secukinumab treatment compared with **4 in 10 children** in the placebo group

More patients achieved and maintained JIA ACR 30 and JIA ACR 70 with secukinumab compared to placebo at two years.

Why does this matter?

The study showed that secukinumab significantly reduces the risk of joint symptoms worsening in children with JPsA and ERA for at least two years.

Current treatment options for JPsA and ERA are limited and only a minority of patients are able to control their disease.[4] Secukinumab could potentially offer a much-needed treatment.

Safety

Secukinumab was well-tolerated with no new or unexpected side effects.

Glossary

Arthritis
[arth-rye-tiss]:
a disease causing painful inflammation and stiffness of the joints.

Biologic medicine:
a treatment made using living organisms, rather than being chemically synthesized.

Enthesitis
[en-thee-sye-tiss]:
inflammation of the entheses, the sites where tendons or ligaments insert into the bone.

Idiopathic
[id-ee-oh-path-ic]:
of unknown cause.

JIA ACR 30/50/70/90/100:
a way to measure improvement in JIA joint disease symptoms, where each number refers to 30%, 50%, 70%, 90% and 100% improvement from a baseline value, respectively.

Juvenile
[joo-vuh-nile]:
for or relating to young people.

Juvenile idiopathic arthritis:
an umbrella term describing seven different types of arthritis in children and teenagers under the age of 16.

Placebo:
a substance with no active component which has no therapeutic effect.

Significant(ly):
statistically, the difference between the groups is unlikely to have occurred by chance. This difference is therefore likely to be related to the medication given to the patients.

Who sponsored this study?

Novartis Pharma AG, Basel, Switzerland sponsored both this study and the writing of this plain language media summary.

Further information

More on this study can be found here:
https://clinicaltrials.gov/ct2/show/NCT03031782

References

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6. Glerup M, et al. *Arthritis Care Res (Hoboken)*. 2020;72 (4):507-516.