Plain Language Media Summary

NOVARTIS

Using sensitive ultrasound imaging to understand response of psoriatic arthritis to secukinumab over 24 weeks

Full abstract title: Responsiveness of Ultrasound Synovitis and Clinical Outcomes in Psoriatic Arthritis Treated with Secukinumab: Data from the ULTIMATE Trial

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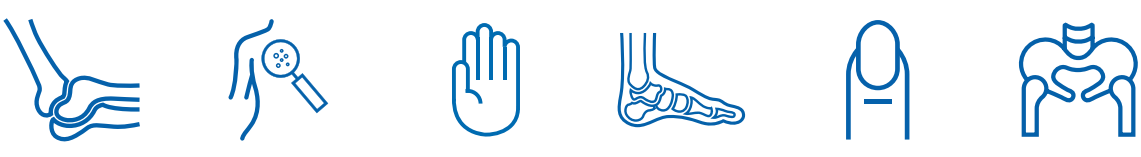
Please note that this summary only contains information from the full EULAR 2021 scientific abstract and selected supporting references. The results of this study may not reflect those of other studies. This summary is not intended to provide medical advice.

Why was this study done?

Psoriatic arthritis (PsA) is a type of inflammatory arthritis that occurs in some patients with psoriasis and is estimated to affect up to 1% of the general public.[1] People with PsA can develop tender and swollen joints caused by inflammation. Inflammation can be good (eg, in fighting infection), but it can also become a problem if it occurs more than needed or happens without a good reason.

The inflammation of the lining of the joints is called synovitis. Research suggests that continued inflammation from PsA can result in joint damage later on;[1] therefore, this is one of the key manifestations of PsA that needs to be managed.

The six key "domains" of PsA:



Joints
About 80% of PsA patients have skin symptoms prior to developing joint symptoms[2]
40-50% of PsA patients may have dactylitis[3]
30-50% of PsA patients may have enthesitis[3]
80% of PsA patients may have nail psoriasis[3]
Up to 70% of PsA patients are impacted by axial involvement[4]

Doctors use different innovative and sensitive imaging techniques to visualize inflammation inside the body, such as magnetic resonance imaging (MRI) and Power Doppler ultrasound (PDUS) scans. PDUS can be used in PsA patients to detect early, smaller changes that may not otherwise be identified and thus can identify disease changes more sensitively.

This study investigated the effect of secukinumab on PsA, using a PDUS standardized and validated ultrasound scoring system.

Ultrasound scans use high-frequency sound waves to build up an image of something inside the body. PDUS is a specific ultrasound technique that can be used to see what is happening to the joints and soft tissue in PsA patients. Compared with other ultrasound techniques, its unique features include its ability to produce detailed, color images from any angle and to detect even small changes.[5]

Secukinumab is a type of medication called a biologic. It helps reduce inflammation by blocking one of the molecules that activates inflammatory cells.[6]

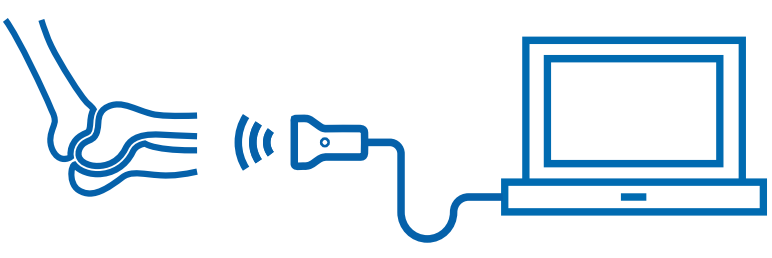
A previous abstract demonstrated that a benefit of secukinumab on synovitis in people with PsA could be seen as early as 12 weeks after treatment. This abstract discusses the 24-week results of the same study.

What did this study look at?

The study looked at how secukinumab treatment affected joint inflammation in patients with PsA over 24 weeks (six months).

To measure the effect of secukinumab on PsA severity, the images collected by PDUS at the start of the study and at 12 and 24 weeks were given a score that reflects the severity of the joint lining inflammation.

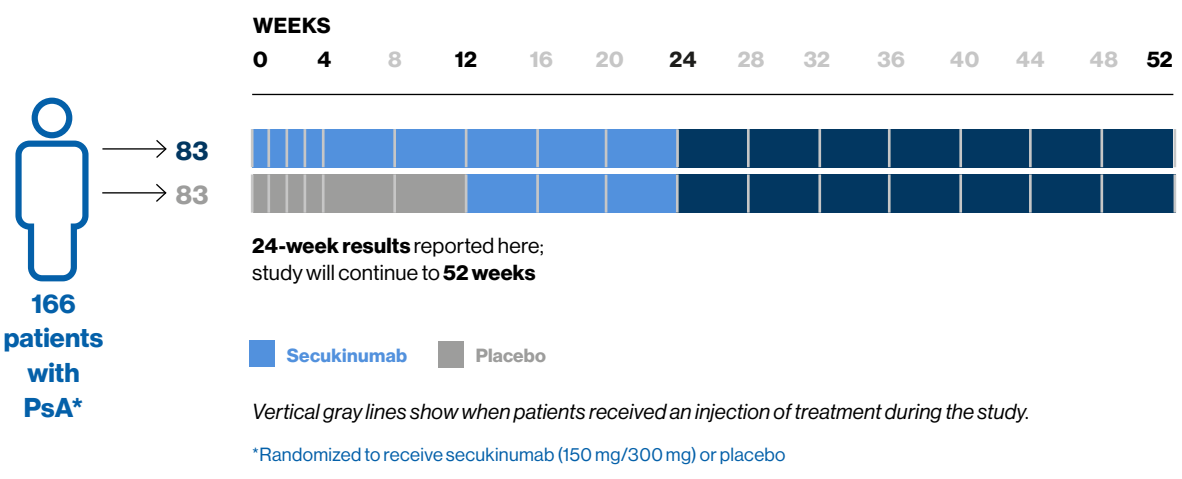
Using PDUS, this study investigated the effects of a treatment called secukinumab on joint inflammation, caused by PsA, using a scoring system to assess changes in synovitis severity.



A variety of other scales were used to score the severity of PsA symptoms. One example, the American College of Rheumatology (ACR) score, is a method of scoring arthritis severity that measures symptom improvement. ACR considers the number of tender and swollen joints, as well as functional ability and markers of inflammation. ACR20 means an improvement of 20%, while ACR50 means an improvement of 50%.

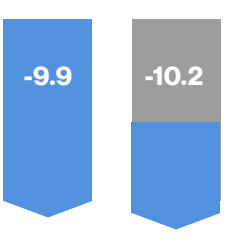
To check if any changes in scores were related to secukinumab, rather than the natural fluctuation of the disease, the results were compared with those of patients receiving a 'dummy' injection containing no treatment (placebo) over the first 12 weeks.

Design of the study

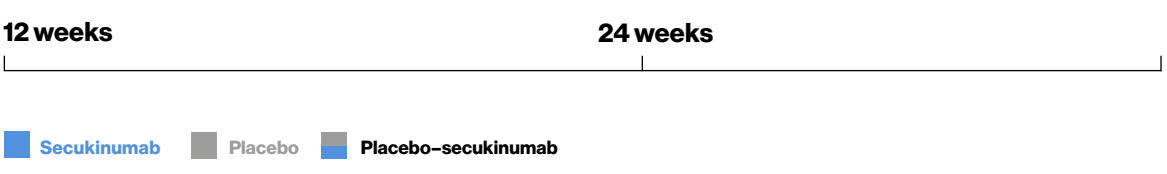


What did this study find?

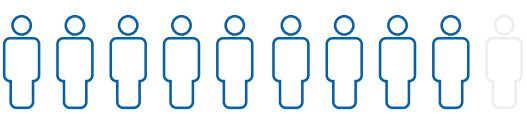
Secukinumab was found to have a significantly **greater benefit** than placebo on PDUS score.



The **small difference** seen between the scores of the placebo–secukinumab and secukinumab-only groups were not found to be significant. There was a similar level of improvement between the placebo-secukinumab and secukinumab-only groups.



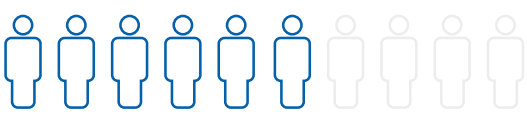
ACR20



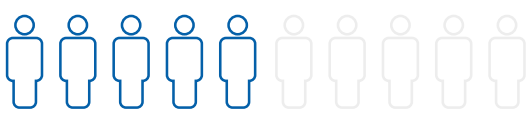
9 in 10 of those in the **secukinumab group** achieved a **20% improvement**

versus **7 in 10** of those in the **placebo–secukinumab group** at Week 24

ACR20



6 in 10 of those in the **secukinumab group** achieved a **50% improvement**



versus **5 in 10** of those in the **placebo–secukinumab group** at Week 24

Overall, using the various scales, sustained improvements in the severity of joint and skin symptoms, dactylitis (inflammation of a finger or toe) and function were seen in both the secukinumab and placebo–secukinumab groups at Week 24. Those who switched to secukinumab at 12 Weeks showed similar level of benefits to those who were treated with secukinumab from the start.

Why does this matter?

This study showed secukinumab can improve joint inflammation in patients with active PsA over 24 weeks (six months).

Secukinumab treatment also showed significant improvement in broader symptoms of PsA, including daily functioning, psoriasis and tender fingers.

Another analysis submitted to EULAR 2021 showed that PDUS can also be used to score enthesitis, which is inflammation that occurs at the points where tendons and ligaments attach to bone. Secukinumab improved enthesitis (that was detected by ultrasound or confirmed by a doctor) over six months.[7]

Clinical trials involving newer imaging techniques can provide further information about a treatment that may be useful to physicians.

Safety

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

Glossary

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

Dactylitis
[dak-te-ly-tis]:
inflammation of a finger or toe.

Enthesitis
[en-tha-sye-tis]:
pain and tenderness in the insertion of the tendon to the bones.

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

Power Doppler ultrasonography (PDUS):
a specific ultrasound technique that can be used to detect early changes on joints, enthesitis, inflammation of digits and skin.

Psoriatic arthritis
[saw-ree-at-ik ahr-thrahy-tis]:
a form of arthritis that affects some people with psoriasis. In PsA, inflammation results in swollen and painful joints and tendons, nail psoriasis, axial symptoms, and swelling of the fingers and toes.

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 treatment given to the patients.

Synovitis
[sye-no-vye-tis]:
inflammation of the joint lining.

The American College of Rheumatology (ACR) score:
a scoring method of arthritis severity that measures symptom improvement.

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 the ULTIMATE study can be found here: https://clinicaltrials.gov/ct2/show/NCT02662985

References

1. Mease PJ, et al. *ACR Open Rheumatol.* 2020;2(1):18-25.
2. Raposo I, Torres T. *Actas Dermosifiliogr.* 2015:106(6):452-457.
3. Ritchlin CT, et al. *N Engl J Med.* 2017;376(10):957-970.
4. Feld J, et al. *Nat Rev Rheumatol.* 2018;14(6):363-371.
5. Radiopaedia. Power Doppler. Available from: https://radiopaedia.org/articles/power-doppler-1?lang=gb [Last accessed: June 2021].
6. Blair HA. *Drugs.* 2019;79(4):433-443.
7. D'Agostino MA, et al. *Ann Rheum Dis.* 2021;80(1):136.